# REPERTORY GRID TECHNIQUE IN THE ASSESSMENT OF QUALITY OF LIFE IN PATIENTS WITH EPILEPSY

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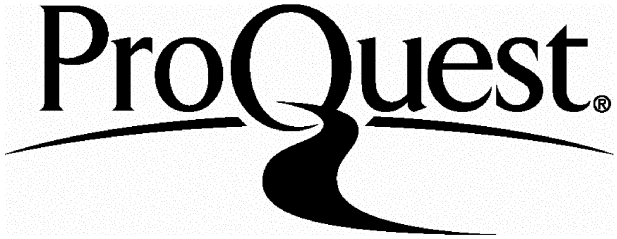

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**ABSTRACT**

A review of currently available measures of quality of life (QOL) highlighted a number of shortcomings which limited their use in assessing the QOL of patients with a heterogenous, chronic disease such as epilepsy. The aim of this study was to develop a method for assessing QOL in patients with epilepsy, but which would also be of value in wider applications. A patient-orientated approach based on repertory grid technique has been developed and tested. A working model of QOL is proposed which makes the following assumptions about the concept: 1) QOL is multi-dimensional, 2) it is an individual phenomena, 3) it is a relational concept and 4) the discrepancy between ability and aspirations is important.

Repertory grid technique enables a standardised, objective yet individualised assessment of QOL to be made. Five core areas of functioning are addressed by the method: physical ability, cognitive ability, emotional status, social functioning and economic/employment status. The psychometric properties (temporal stability, sensitivity and validity) of the method were assessed in a group of fifty patients with chronic epilepsy who were studies prospectively over a six month period (baseline, 1 month, 3 months, 6 months). In addition, a number of other questionnaires were completed on these occasions including a non-specific, generic QOL measure, a mood scale, a life events scale and a global rating of life satisfaction. Variables relating to epilepsy such as seizure frequency and change of medication were also closely monitored. A small study in a group of patients undergoing surgery for the relief of severe facial pain (trigeminal neuralgia) was conducted to provide additional evidence relating to the sensitivity of the method.

A number of outcome measures were subjected to psychometric assessment including five global scores (ABS, DIR, ABS21, ABS6, DIR6) and five profile scores (PHYS, COG, EMOT, SOC, WORK). The findings suggest that the novel method is a reliable, sensitive and valid procedure. It is hoped that this method will provide a useful tool in evaluations of the effects of epilepsy and its treatment on patient-perceived QOL.

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**GLOSSARY OF ABBREVIATIONS**

| | |
|---|---|
| AED | Antiepileptic drug |
| ABS | Aggregate repertory grid score |
| ABS6 | Aggregate repertory grid score |
| ABS21 | Aggregate repertory grid score |
| BEFORE | Element: 'as you were before having epilepsy' |
| BEST | Element: ' the best life imaginable' |
| CBZ | Carbamazepine |
| CIS | Construct Importance Scale |
| CLB | Clobazam |
| COG1 | Repertory grid cognitive profile score (method 1) |
| COG2 | Repertory grid cognitive profile score (method 2) |
| CPS | Complex partial seizure |
| DIR6 | Aggregate repertory grid score |
| DIR21 | Aggregate repertory grid score |
| EP | Epilepsy group |
| EMOT1 | Repertory grid emotional profile score (method 1) |
| EMOT2 | Repertory grid emotional profile score (method 2) |
| EXPECT | Element: 'as you expect to be' |
| FRIEND | Element: 'as a close friend is' |
| FSIQ | Full scale IQ |
| GRS | Global Rating Scale |
| GRS1 | Satisfaction with life in general |
| GRS2 | Satisfaction with physical abilities |
| GRS3 | Satisfaction with cognitive abilities |
| GRS4 | Satisfaction with emotional status |
| GRS5 | Satisfaction with social functioning |
| GRS6 | Satisfaction with employment |
| GRS7 | Satisfaction with finances |
| IA | Simple partial seizure |
| IB | Complex partial seizure |
| IC | Secondary generalised seizure |
| IIA | Absence seizure |
| IIB | Myoclonic seizure |
| IID | Tonic seizure |
| IIE | Tonic-clonic seizure |
| IIF | Atonic seizure |
| KPI | Karnofsky Performance Index |
| LE | Life event group |
| LES | Life Events Schedule |
| LIKE | Element: 'as you would like to be' |
| MACL | Mood Adjective Checklist |
| MACL-D | Mood Adjective Checklist Depression sub-scale |
| MHIQ | McMaster Health Index Questionnaire |
| NHP | Nottingham Health Profile |
| N-L | Now-Like distance |
| NOW | Element: 'as you are now' |
| PAIS | Psychosocial Adjustment to Illness Scale |
| PG | Primary generalised seizure |
| PHB | Phenobarbitone |
| PHYS1 | Repertory grid physical profile score (method 1) |
| PHYS2 | Repertory grid physical profile score (method 2) |
| PIQ | Performance IQ |
| PRIM | Primidone |
| QALY | Quality adjusted life year |
| QOL | Quality of life |
| QOLAS | Quality of Life Assessment Schedule |

| | |
|---|---|
| RG | Repertory grid |
| SIP | Sickness Impact Profile |
| SIP-AMB | Ambulation dimension score |
| SIP-AB | Alertness behaviour dimension score |
| SIP-BCM | Bodycare and movement dimension score |
| SIP-COM | Communication dimension score |
| SIP-EAT | Eating dimension score |
| SIP-EM | Emotions dimension score |
| SIP-HM | Household management dimension score |
| SIP-REC | Recreation dimension score |
| SIP-SI | Social interaction dimension score |
| SIP-SR | Sleep and rest dimension score |
| SIP-WK | Work dimension score |
| SIP-PHYS | Physical category score |
| SIP-SOC | Psychosocial category score |
| SIP-TOT | Total disability score |
| SOC1 | Repertory grid social profile score (method 1) |
| SOC2 | Repertory grid social profile score (method 2) |
| SPS | Simple partial seizure |
| S1 | Session 1 (baseline) |
| S2 | Session 2 (1 month) |
| S3 | Session 3 (3 months) |
| S4 | Session 4 (6 months) |
| TN | Trigeminal neuralgia group |
| VIQ | Verbal IQ |
| VPA | Sodium valproate |
| WORK1 | Repertory grid economic/employment profile score (method 1) |
| WORK2 | Repertory grid economic/employment profile score (method 2) |
| WORST | Element: 'the worst life imaginable' |
| WPSI | Washington Psychosocial Seizure Inventory |
| 2GEN | Secondary generalised seizure |

# CHAPTER 1
# QUALITY OF LIFE

## 1.1 BACKGROUND

Quality of life (QOL) is a much used yet ill-defined term. As Campbell (1976) states: "Quality of life is a vague and ethereal entity, something that many people talk about, but which nobody very clearly knows what to do about".

This chapter will attempt to define QOL and to examine the factors that are important in determining the QOL of an individual. The QOL literature is vast with contributions from many fields of research. The literature can be broadly divided into three main areas 1) the work of the social indicators movement. 2) the psychological literature pertaining to 'satisfaction', 'well-being' and 'happiness' and 3) the medical literature. The emphasis of this thesis is on the impact of illness on QOL and hence much of the literature reviewed will be biased towards this area. However, work and ideas generated in other fields of research are of value in attempting to gain a general perspective and understanding of what we mean when we talk about 'quality of life'.

### 1.1.a The Social Indicators Movement

The beginnings of QOL research can be traced back to the work of the social indicators movement in the early 1960's. The social indicators movement came into being in response to the need for measures to describe and monitor changes in the population relating to areas such as housing, employment, health provision, political participation and population growth and movement. Thus, it was concerned with QOL at a group or population level. Data collected in large scale surveys were used to compare areas of population (for example, comparisons of urban and rural communities), determining population needs and monitoring the success (or failure) of social policies. Much of the published literature originated in the United States, with data from these studies often being equated with the 'quality of life' of the population. This approach initially viewed QOL in purely objective terms. For example, the QOL of the population was equated with factors such as the percentage unemployed, percentage below the poverty level and national average income. The assumption was made that the higher the number of people in employment, the

higher the average wage and the higher the standard of living the greater was the QOL of the population. Following on from this, a rise in income levels or home ownership was taken to indicate increased satisfaction with life.

The limitations of this purely objective approach to determining the QOL or well-being of the population became apparent in studies such as that of Campbell et al. (1976) who reported declining levels of satisfaction in the population between 1957 and 1972, whilst during the same period the majority of economic and objective social indicators (average wage, standard of living) were on an upward trend. This led Campbell (1976) to query the extent to which purely objective measures could be used as valid and useful indicators of the QOL experience. He argued, as a psychologist, that "quality of life lies in the experience of life". Thus, in order to address QOL, Campbell (1976) felt it was necessary to develop measures which tapped the individuals feelings of general well-being as opposed to simply describing the conditions in which he lived. Thus, the 1970's saw an increasing shift away from the traditional objective approach towards attempts to devise subjective measures of QOL.

Two important publications during this era, both of which attempted to address the subjective nature of QOL were the monograph by Campbell et al. (1976) entitled 'Quality of American Life: Perceptions, Evaluations and Satisfaction' and the book by Andrews and Withey (1976) 'Social Indicators of Well-Being: American Perception of Life Quality'. Both of these publications report the findings of large scale surveys which were conducted to define and describe the subjective well-being of the American population. This involved determining what areas were of importance to the QOL of the American population and devising and testing subjective indicators of these areas. In addition, the relationship between QOL and a number of socio-demographic attributes, for example age, sex and marital status was investigated. These were the first large scale national surveys to directly address the subjective nature of QOL.

In summary, the origins of studies evaluating QOL can be seen in the social indicators movement and it has

contributed both to our understanding of the concept of QOL and its measurement. The limitations of a purely objective assessment of QOL has been recognised and attempts to devise more subjective measures of QOL undertaken as evidenced by the work of Campbell et al. (1976) and Andrews and Withey (1976). However, while the shift towards the evaluation of the subjective nature of QOL is recognised (Hollandsworth, 1988) and welcomed, care needs to be taken to ensure that objective measures are not totally ignored. QOL is a complex phenomena and an interaction between objective and subjective factors in its determination is probable.

### 1.1.b The Psychological Literature

It is interesting that the term 'quality of life' has only recently found its way into the psychological literature. This does not, however, reflect the fact that psychologists have been uninterested or uninvolved in this field, but rather they have called it something else. A search of Psychological Abstracts revealed many phrases/concepts which could be considered analogous to QOL, for example 'well-being', 'satisfaction' and 'happiness'. Indeed, in the QOL literature the term is often used interchangeably with these concepts, with general definitions often including such terms. Szalai (1980), for example, defines QOL as "the global evaluation of the good or satisfactory nature of people's lives". In a similar vein, Dalkey and Rourke (1973) define QOL as "a persons' sense of well-being, his satisfaction/dissatisfaction with life or happiness/unhappiness in dimensions of health, activity, stress, life-goals, self-esteem, depression, social and family support".

An important point to note here is the distinction between 'satisfaction' and 'happiness'. The appropriateness of using the term 'happiness' as an indicator of QOL has been questioned (Goodinson and Singleton, 1989). They suggest that happiness is an ephemeral state, something which is in constant flux and dependent on mood, and is thus an inaccurate indicator of QOL. In contrast, satisfaction is seen to involve a cognitive component in which a comparison with some external criteria is made (Campbell et al., 1976) and is therefore more

likely to accurately reflect the QOL of the individual. In this review of the psychological literature relating to QOL, this distinction has been followed and work relating to determinants of 'happiness' or 'affective state' have not been included. In this thesis the term QOL is used interchangeably with related concepts such as 'well-being' and 'satisfaction'.

The psychological literature pertaining to 'well-being' and 'life satisfaction' can be divided into two main areas, 1) those reporting the findings of empirical studies and 2) those concerned with philosophical issues. The empirical studies reported attempt to address a number of issues relating to QOL. Correlational studies have attempted to address the question of what aspects of life functioning are important to QOL. The influence of demographic variables such as age, sex and personality have also been studied. Such studies aid our understanding of what is important to QOL. In addition, they enable us to determine how these areas of importance alter in differing circumstances, for example in relation to growing older or differences between men and women or between the employed and unemployed.

The second body of literature concerns the philosophical approach to QOL. How do we determine our feelings of 'well-being'? What do we use as our criteria? Are these criteria internal or external? This literature introduces concepts such as the attainment of life goals, achievement-aspiration discrepancy and needs satisfaction. These concepts are discussed in more detail in the section on the conceptualisation of QOL (Chapter 1, Section 1.3).

### 1.1.c Quality of Life in Medicine

The use of QOL as a health status indicator is a relatively new phenomena, but has received increasing prominence in recent years. This increasing use of QOL in the health care field has arisen as a result of the increasing prevalence of patients with chronic disease, advances in medical knowledge and an associated decline in the relevance of traditional health status indicators such as mortality and morbidity. Such indicators, while of undoubted value in acute conditions are of lesser relevance in chronic conditions in which

treatment is often not curative and may bring with it unwanted side effects.

There are two main applications of the QOL concept in the medical sphere. Firstly, at the clinical level, studies have investigated how illness and its treatment impacts on the QOL of the individual. Much of the pioneering work in this field has been conducted in the fields of oncology (Spitzer et al., 1981; Fayers and Jones, 1983; Selby et al., 1984; de Haes and Knippenberg, 1985; Clark and Fallowfield, 1986), cardiovascular disease (Wenger et al., 1984a; Croog et al., 1986; Williams, 1987; Wenger, 1989), rheumatology (Meenan et al., 1980) and respiratory disease (McSweeney, 1984).
The main thrust of this research has been to determine the benefits to the patient of various treatments, both pharmaceutical and non-pharmaceutical. For example, studies have examined the comparative benefits, in terms of QOL, of breast-sparing surgery versus total mastectomy in women with breast cancer. In addition, the pharmaceutical industry has become increasingly interested in QOL. For many chronic illnesses, there exist a number of competing pharmaceutical agents which are of equal effectiveness, differing only in their side-effect profile. The impact of these side-effects on a patients' QOL may well be the determining factor in the decision to use or not use a particular agent.

A review of the clinical application of QOL to medical research provides some insight into how illness and disease can impact on the QOL of the patient. A number of working definitions have been proposed by various authors and measurement tools developed. Thus, the medical literature can provide information relating not only to the impact of illness on QOL, but also to the definition and measurement of QOL. The measurement of QOL is discussed in detail in Chapter 3. In addition, comparisons with work conducted in healthy populations, such as that reported in the psychological literature, will be of interest in determining if the concerns of patients are vastly different from those of healthy individuals.

The second application of QOL data is as a means of calculating cost-benefit analyses. Health care managers/policy

makers often need to determine and compare the relative effectiveness of different treatments, both in terms of benefit to the patient and cost to the nation of that treatment. This has resulted in the creation of the term QALY (Quality Adjusted Life Years). In simple terms, QALYs are an amalgam of quantity (duration) and quality of life. Various economic theories have been applied to the determination of QALYs, the most popular being utility theory (Torrance, 1973; Sackett and Torrance, 1978; Kaplan and Bush, 1982; Williams, 1985; Torrance, 1986; Torrance, 1987; Liang and Robb-Nicholson, 1987; Loomes and McKenzie, 1989; Carr-Hill, 1989). A detailed discussion of the QALY literature is not of direct relevance to, and beyond the scope of this thesis. However, some of the major approaches will be discussed further in the chapter on measurement (Chapter 3, Measurement of QOL).

### 1.1.d Summary

The above section has attempted to place current QOL research in context and to outline the main sources of information upon which this thesis is based. Work conducted in these various fields has been drawn together in an attempt to gain a clear understanding of what constitutes QOL. The primary aim of this thesis is to develop a method of assessing QOL in patients with chronic epilepsy. However, before this can be attempted, the following issues need to be addressed in order to arrive at a working definition of QOL:

1) what is QOL? (Definition)
2) how do we determine our QOL? (Conceptualisation)
3) how is QOL influenced by socio-demographic variables such as age and sex? (Demographic influences)

The following sections attempt to answer these questions.

## 1.2 DEFINITION

### 1.2.a General definitions

In the QOL literature, there appear to be as many definitions of QOL as there are authors! A selection of general definitions of QOL are shown in Table 1.1. These serve to highlight the different approaches to the definition of QOL and illustrate the problems in reaching a concise, workable definition of QOL.

Table 1.1: Examples of general definitions of QOL

| |
|---|
| "The well-being of an individual is related to the extent that he (a) takes pleasure from whatever the round of activities that constitutes his everyday life; (b) regards his life as meaningful and accepts resolutely that which life has been; (c) feels he has succeeded in achieving his major goals; (d) holds a positive image of self; (e) maintains happy and optimistic attitudes and mood". (Neugarten et al., 1961) |
| " A person's sense of well-being, his satisfaction / dissatisfaction with life or happiness / unhappiness in dimensions of health, activity, stress, life-goals, self-esteem, depression, social and family support". (Dalkey and Rourke, 1973) |
| QOL is "the totality of those goods, services, situations and state of affairs which are delineated as constituting the basic nature of human life which are articulated as being needed and wanted". (Harwood, 1976) |
| "Living in the authentic self, living in harmony with nature, living at peace with God, living in the fulfilment of our children, living at ease in our own mind, living our own biological heritage". (Meares, 1976) |
| "The global evaluation of the good or satisfactory nature of people's lives". (Szalai, 1980) |
| "The essence of QOL is found in the circumstances of existence itself: the ability to perform the ordinary activities of daily living and to interact effectively with the environment". (Alexander and Willems, 1981) |
| Overall evaluation of the subjective experience of life" (DeHaes and Knippenberg, 1982) |
| "Degree of satisfaction with perceived present life circumstances". (Young and Longman, 1982) |
| "The ability of an individual to perform his or her social roles and the degree to which enjoyment or satisfaction is derived from performing these roles". (Levine and Croog, 1984) |
| "A wide and general definition of the concept of QOL encompasses the individuals capacity to function within the context of work, social role and family as well as his physical, emotional, mental and intellectual capacity. The individuals perception of and satisfaction with the way in which he functions is perhaps most important". (Wiklund et al., 1986) |
| "QOL is a collective term that encompasses multiple components of a persons social and mental status. Simply stated, it is the ability of a person to function normally in society, as perceived by the person". (Williams, 1987) |

Quality of life is a generic, broad term covering all aspects of human functioning. Another term which is widely used in the medical literature and warrants a separate definition here is Health-Related Quality of Life (HRQOL). This is a much more specific definition of QOL, restricting it to the impact of illness (or its treatment) on QOL. Patrick and Erickson (1987) defined HRQOL as "the levels of well-being and satisfaction associated with events or conditions in a persons life as influenced by disease, accidents or treatments". In a similar vein, Schipper et al. (1990) state that HRQOL "represents the functional effect of an illness and its consequent therapy upon a patient, as perceived by the patient".

In summary, while there is wide variation in the definition of QOL, two common themes can be identified. First, many of the definitions stress the individual nature of QOL, thus it is the feelings or perceptions of the individual which are important is determining their QOL. Second, the multi-dimensional nature of QOL is recognised. QOL is a complex amalgam of a variety of aspects of life functioning.

### 1.2.b Working definitions: Some examples

General definitions attempt to encapsulate in a sentence or two the complex nature of QOL. Working definitions of QOL are more detailed analyses of the QOL phenomena and have often been proposed by researchers as a prelude to choosing or devising measures to assess QOL. The following section will outline a selection of published working definitions from the medical sphere in an attempt to more fully understand the nature of the QOL concept and how illness can impact on it.

There is a growing acceptance among workers in this field as to the general life domains which contribute to feelings of satisfaction with life. In 1980, the World Health Organisation, in recognition of the increasing need to monitor the consequences of disease and treatment on patients' lives, published a set of guidelines entitled 'International Classification of Impairments, Disabilities and Handicaps' (WHO, 1980). In this, they outline six areas they consider important to adequate functioning (and hence, QOL). These are

orientation, physical independence, mobility, occupation, social integration and economic self-sufficiency. These are viewed as minimal survival roles, thus it is stated " one can identify certain fundamental accomplishments that are related to the existence and survival of man as a social being and are expected of the individual in virtually every culture" (WHO, 1980). This theme of a core of life domains essential to determining QOL can be seen throughout the literature relating to this topic, with much convergence being evident (see Table 1.2).

A number of working definitions of QOL, based on a set of core domains have been proposed and some of these are discussed in greater depth below. As the emphasis of this thesis is the determination of QOL in patients with a chronic disease (epilepsy) the working definitions reviewed have been restricted to those assessing the impact of illness on QOL.

Spitzer (1987) discusses a general conceptual model (originally proposed by R Meehan, no reference given) for the measurement of the impact of health/illness on QOL. This is illustrated in Table 1.3. Three levels of operation are suggested: the conceptual level, the operational level and the measurement level. QOL is seen as consisting of three spheres of functioning: physical, social and mental abilities. Within these general areas, specific areas of functioning which need to be addressed in the overall assessment of QOL are defined. For example, mobility and the ability to perform self-care activities (activities of daily living) are specific aspects of the physical functioning domain. Similarly, the 'social' umbrella may be more precisely defined to included employment, social interactions and relationships with family and friends. This sub-division process provides an operational definition of QOL. The third and final layer relates to specific symptoms, and particularly those aspects which are expected/hypothesised to be influenced by the disease process or treatment being studied. Thus, nausea may be an important component in assessing the QOL of the cancer patient receiving chemotherapy, but may be of no relevance to the patient with a broken leg, for whom the ability to walk may be of greater importance. This final process results in the definition of a

Table 1.2: Examples of core domains important to QOL of life proposed by selected authors.

| | WHO (1980) | Hornquist (1982) | Wenger et al (1984) | Spitzer (1987) | Ware (1987) | Fallowfield (1990) |
|---|---|---|---|---|---|---|
| Physical | + | + | + | + | + | + |
| Psychological* | + | + | + | + | + | + |
| Social | + | + | + | + | + | + |
| Occupation | + | + | + | | | + |
| Economic Status | + | + | + | | | |
| Structural | | + | | | | |
| Role Functioning | | | | | + | |
| Perceptions | | | + | | | |
| Symptoms | | | + | | | |

* includes cognitive/intellectual and emotional factors

Table 1.3: Conceptual model for measurement of QOL (Spitzer 1987)

| Conceptual level | PHYSICAL | SOCIAL | MENTAL |
|---|---|---|---|
| Operational level | Mobility<br>ADL | Work | Anxiety<br>Cognition<br>Mood |
| | Specific symptoms | | |
| Targets for hypothesis-based measrures | Walking<br>Speech<br>Nausea | Pain | Memory<br>Fear |

number of functions for which measures need to be devised or found.

This is a very simplistic approach which only encompasses the multi-dimensional nature of QOL and then only three domains are considered. No discussion of the individuals perceptions of or satisfaction with their abilities is made. Such a model is a useful starting point, but leaves many questions unanswered, for example, who sets the targets for the hypothesis-based measures? Is it an 'expert' in the health care profession or the patient themselves?

Individual perceptions are incorporated into the working definition of QOL proposed by Levine and Croog (1984) by the introduction of a dimension entitled 'general well-being'. These researchers working in the field of cardiovascular disease suggest five essential elements to the QOL construct: performance of social roles, physiologic state, emotional state, intellective functioning and general satisfaction or well-being (see Table 1.4). The authors believe that an essential element of QOL is its social nature, stating that "people are social beings who live in a social environment and who perform basic social roles such as those of spouse, parent, worker, friend and citizen". A major component of QOL is thus "the ability of an individual to perform his or her social roles and the degree to which enjoyment or satisfaction is derived from performing these roles".

A slightly different approach to the conceptualisation of QOL is reported by Wenger et al. (1984b). Again, working with patients with cardiovascular illness, it is suggested that QOL may be defined in terms of three major components: functional capacity, perceptions and symptoms (see Table 1.5). As in the proposal by Levine and Croog (1984), functional capacity incorporates five areas of functioning namely physical ability, social function, intellectual function, emotional state and economic status. Physical ability relates to the ability to carry out activities of daily living (self-care), mobility, independence, getting adequate sleep and rest and participation in occupational and recreational activities. Social functioning covers

Table 1.4: Working definition of QOL: Levine and Croog (1984)

| DIMENSION | SPECIFIC ITEMS |
|---|---|
| Social Roles | Work<br>Family activities<br>Community activities<br>Relationships with friends and acquaintances |
| Physiologic State | Mobility<br>Pain<br>Symptoms eg. nausea, weakness |
| Emotional State | Anxiety<br>Feeling of stability and self control<br>Depression |
| Intellective functioning | Alertness<br>Memory<br>Confidence in decision making<br>Side effects of treatment on cognitive function |
| General sense of well-being | Approaching each day with interest, vitality and enthusiasm<br>Spiritual well-being<br>Sin/guilt/conflicts with religion<br>Concern about relationship with God |

Table 1.5: Conceptualisation of QOL: Wenger et al (1984)

| DIMENSION | SPECIFIC ITEMS |
|---|---|
| FUNCTIONAL CAPACITY | |
| Physical ability | self-care<br>mobility<br>independence<br>sleep and rest<br>recreational activities |
| Social function | social activities<br>relationships with family<br>marital satisfaction |
| Intellectual function | memory<br>communication<br>decision making |
| Emotional state | mood changes<br>guilt, hostility<br>sick role behaviour<br>fears<br>expectations/satisfactions |
| Economic status | income<br>employment |
| PERCEPTIONS | health status<br>values and belief system |
| SYMPTOMS | frequency<br>severity<br>hospitalisation<br>medication<br>side effects of treatment |

participation in social activities with friends, relationships with family and marital satisfaction. Intellectual function incorporates abilities such as memory, alertness, the ability to communicate, decision making and forming judgements. Emotional status refers to a wide range of emotions and feelings including mood changes, feelings of guilt, hostility, depression, helplessness, satisfactions, expectations and fears and concerns about the future. Also included in this domain is sick role behaviour. Finally, economic status relates to the ability of the individual to maintain a satisfactory standard of living. This may be assessed by variables such as income, employment and early retirement on the grounds of ill-health.

An important addition in this definition, over and above those of other working models reviewed here, is the emphasis placed on the important role played by individual perceptions. Perceptions relate to changes in functional capacity that the individual themselves see as important to their QOL ie. as they relate to that individuals' value system, beliefs and perspectives. The implication of this is that the only person who can reliably assess their QOL is the individual themselves; it is an individuals own perceptions of their health and functional status which are the important determinants of their QOL. This is of significance when choosing or devising measures of QOL. The issue of who should assess QOL is discussed further in Chapter 3 (Measurement of QOL).

The final major component to QOL proposed by Wenger et al. (1984) is symptoms. These are of particular relevance when assessing the QOL of an individual with a chronic disease. It is suggested that the symptoms associated with an illness and its treatment play a critical role in influencing the QOL of the patient with that illness. QOL may be influenced by a variety of factors including the severity of the symptoms, the frequency with which they occur, the need for repeated hospitalisations, the amount of medication needed to reduce symptoms and the side-effects of treatment.

1.2.b.i **Summary**

It is possible to identify a finite number of broad key domains of life which are important components of the QOL concept. These can be summarised as follows:

- physical functioning
- cognitive/intellectual functioning
- emotional status
- social functioning
- economic/employment status

The importance of an individuals perceptions has also been raised. Another issue which is of relevance here is the relative importance of each domain. If all domains are of equal importance then changes in satisfaction within various domains may result in no change in overall QOL. However, if one domain is of extreme importance to the individual then changes within this domain may dramatically affect overall QOL, while changes within a less important domain may not affect QOL. This issue is discussed by Campbell (1981, page 20).

Given that it is possible to identify these key domains, the next question that arises is: what specific aspects of these key domains are important to QOL? The precise definition of QOL is a problematic area. Everyone has their own idea as to what QOL is, and therein lies the problem; what is of extreme importance to one individual may be of no relevance to another. Reaching a consensus as to what specific items are important to QOL has yet to be achieved, if indeed this is feasible or desired. A number of empirical studies have attempted to define what aspects of life are important to QOL and the findings of these will be reviewed in the following section.

1.2.c **Empirical studies of areas important to QOL**

A number of studies have attempted to identify, within limited populations, what aspects of life functioning are predictive of satisfaction with life or QOL. The studies fall into two main types: correlational and investigative. In the former, a number of objective and subjective measures of functioning are assessed and correlated with some measure of life

satisfaction. Some studies have also employed multiple regression type analyses to establish the predictive value of a range of independent variables to predicting satisfaction. One major limitation of this type of study is that only the independent variables assessed can be entered into the analysis and these are often chosen by the investigator, not the population being assessed. The latter type of study asks respondents either to identify or rate selected items in terms of their importance to QOL. Formal analyses (such as factor analysis) are then employed to determine the most potent items. This approach is often employed by developers of questionnaires.

### 1.2.c.i **Correlational studies**

Bortner and Hultsch (1970) investigated a number of objective and subjective factors in relation to overall life satisfaction in 1,406 respondents (mean age 45.6 years) in the United States. Life satisfaction was assessed using the Cantril ladder (Cantril, 1965). In this self-anchoring method, subjects are asked to describe the worst possible and best possible life for them. These descriptions are used as the end-points of an 11-point ladder and subjects are asked to rate their current life situation along the ladder. A multiple regression analysis was employed to determine the predictive ability of the independent variables. The findings suggest that socio-psychological variables were more important determinants of life satisfaction that demographic data. Thus, the five variables which were most predictive of life satisfaction were: success in achieving goals/aims in life, having the opportunity to do what you want to do, present life situation, presence/absence of troubles and obstacles and feelings of self-respect. In contrast, demographic data such as age, sex, economic level, race, education, occupation and marital status showed low correlations to overall life satisfaction. The authors also noted that a combination of variables were more predictive of life satisfaction than any one single item, thus highlighting the multifactorial nature of QOL.

Palmore and Luikart (1972) investigated the relative importance of a number of variables assessing health, activity, social-psychological aspects and economic status (see Table 1.6 for full details) to life satisfaction in middle-aged and elderly Americans. 502 healthy adults aged 45 to 69 years participated in the study. The Cantril ladder was used to assess life satisfaction. Factors which correlated significantly with feelings of life satisfaction were: self-rated health, organisational activity (number of religious services and meetings of other groups such as clubs, unions and associations attended), feelings of internal control, performance status (a rating of health made by a physician) and productive hours (number of hours spent working or doing household duties, voluntary work, gardening, repairs etc). This study suggests that four life domains are pertinent to QOL: physical status (self-rated health, performance status), social functioning (organisational activity), emotional status (feelings of internal control) and economic/employment status (income, productive hours). The influence of demographic variables on QOL is discussed in detail in a later section, however, this study found demographic factors, with the exception of income, to be weak predictors of life satisfaction.

Edwards and Klemmack (1973) looked at a variety of factors influencing life satisfaction, as measured by 10 items of the Life Satisfaction Index (Adams, 1969). 22 variables covering socioeconomic state, personal/social background, formal social participation, informal interaction with family, informal non-familial participation and health status were assessed (see Table 1.7). 507 American adults aged over 45 years of age were included in the study. No details of upper age limit or the mean age of the group is given. Results of multiple regression analysis indicated three factors which are important in predicting life satisfaction: socioeconomic status, perceived health and informal participation with non-family members. This highlights the importance of physical, economic and social domains to QOL. It is of interest that perceived health was more predictive than the objective measures of health. The specificity of the influence of the

Table 1.6: Variables investigated by Palmore and Luikart (1972) as predictors of life satisfaction

| DOMAIN | VARIABLE |
|---|---|
| Health | Self-rated health |
| | Performance status (rating by physician) |
| Activity | Organisational activity |
| | Social activity hours |
| | Productive hours |
| | Social contacts |
| | Employment |
| Social-psychological | Internal control |
| | Career anchorage |
| | Having a confidante |
| | Marital status |
| | Sexual enjoyment |
| | Moves |
| | Intelligence |
| Socio-economic | Income |
| | Education |
| | Age |
| | Sex |

Table 1.7: Variables investigated by Edwards and Klemmack (1973) as predictors of life satisfaction

| DOMAIN | VARIABLE |
|---|---|
| Socio-economic status | Education |
| | Income |
| | Occupational status |
| Background data | Age |
| | Sex |
| | Marital status |
| | Family size |
| | Time in area |
| | Community size |
| | Retired (head of household) |
| Formal participation | Voting |
| | Voluntary associations |
| | Church-related activities |
| Informal family participation | Visits to/from relatives |
| | Visits to/from relatives |
| Informal non-family participation | Visits to/from neighbours |
| | Frequency of phone calls |
| | Number of neighbours |
| | Number of friends |
| Health | Perceived health |
| | Number of ailments in last month |
| | Number of ailments in last year |

social variables studied (predictive value for informal non-familial participation, but not for family interactions) highlights the individual nature of QOL and suggests that, in this population at least, it is not social activity per se which is important, but the specific nature of the social activity. The type of social activity which is important to overall life satisfaction may vary as a result of individual differences such as age or personality. The role of social support as a mediator is discussed further in a later section.

Many studies have investigated several aspects of life which may be important to QOL, while others have concentrated on one specific feature. An example of a more limited approach can be seen in the study by Hughey and Bardo (1987) who looked at the relationship between satisfaction with community and overall QOL. The rationale behind the study was that the community is where most of life is experienced and where most people engage in their day to day activities. A relationship between satisfaction with the community and overall QOL would, therefore, be expected. 250 randomly selected residents of Knoxville, Tennessee took part in the study. Satisfaction with community was assessed with the Community Satisfaction Scale (Bardo and Hughey, 1984). This 54-item scale was reduced through factor analysis to provide scores on 3 factors: 1) alienation from generalised others, 2) belongingness and quality of community life, 3) care for community by others and institutions (local government etc). Perceived overall QOL was assessed using the Cantril ladder (Cantril, 1965). Subjects were asked to rate their lives as they were 5 years ago, as they are at present and how they expect to be in 5 years time. The ratings for these three assessments were combined to provide an overall QOL score. Multiple regression analysis demonstrated that the best predictors of overall QOL were feelings of belonging to the community and care for community by others. Overall, satisfaction with community accounted for 10% of the variance in QOL scores, suggesting that while aspects of the community are important to QOL, other factors also have a role to play. This study suggests that subjective appraisal of community is important to QOL. It does not, however, allow a comparison of

subjective and objective (for example, housing, state of roads, education) measures of community life in relation to their influence on feelings of QOL.

1.2.c.ii **Investigative studies of factors important to QOL**

The above studies have investigated correlations between selected variables and ratings of life satisfaction. A different approach to determining what aspects of functioning are considered important to QOL is seen in a study by Berg et al. (1976) in the United States. This study asked 150 health workers to rate 50 items of individual function on a scale ranging from 1 to 10 in terms of their value to the quality and meaningfulness of life. The ten most important areas of functioning were: 1) to be able to use mental abilities, 2) to be able to love and be loved, 3) to be able to think clearly and be clear of confusion, 4) to be able to see, 5) to be able to use your hands, 6) to be able to have friends, 7) to be able to make decisions for yourself, 8) to be able to live at home, 9) to be able to maintain contact with family and friends, 10) to be able to talk. An open-ended question elicited some interesting suggestions including: to be able to do things on the spur of the moment, to be able to blend in with the crowd, to be able to feel all emotions, to be able to maintain self-esteem, to be able to travel, to be able to participate in sports and to be independent, even with assistance. In summary, this study highlights the importance of cognitive, emotional and social functioning to QOL. The authors conclude that QOL studies need to focus on the perceptions of the individual, determining what their particular concerns are and how they relate to feelings of well-being.

Krupinski (1980) conducted a study in Melbourne, Australia in which respondents were asked to rate how important different aspects of life were to them and to complete a diary indicating how they had spent their time over a one week period (both in terms of type of activity and time spent on that activity). In addition, levels of physical function and psychiatric state were determined. The sample consisted of 3,150 respondents. The aspects of life included

in the importance ratings were: 1) life in general, incorporating family life, being free from worries, material security, personal relations, being in useful employment, recreation and beliefs and ideas, 2) work, assessed by feelings of independence/dependence in the work situation, conditions of employment and freedom from pressure, 3) housing, in particular having a house with a garden, having a flat better than neighbours. A number of school children were also included in the study, who completed questions concerning school instead of those relating to work. The specific questions about school were: educational setting, peer activities, closeness to home and rules. Analysis of the importance ratings indicated that, in adults, social (family, personal relations), emotional (freedom from worries) and economic (material security, having house with garden, work in general, being usefully employed) considerations were rated to be the most important aspects of life satisfaction. In school children a similar pattern of results was seen with school replacing work as being important to life satisfaction.

Jenkins et al. (1990) proposed a conceptual model of QOL, defined appropriate endpoints based on available questionnaires and using factor analysis compared the factors derived from the data to those proposed. A good fit was seen in over 500 post-operative heart surgery patients. Five factors were identified by factor analysis as being of importance to QOL: low morale, symptoms of the illness, neuropsychological function, interpersonal relationships and economic/employment situation.

1.2.c.iii **Summary**

Despite wide variations in study design, populations and variables investigated, a number of common themes are apparent. First, the multidimensional nature of the QOL concept is highlighted. Variables which show correlations with life satisfaction scores generally fall within the five broad domains outlined previously: physical, cognitive, emotional, social and economic/employment. In addition, a similar pattern of concerns is noted when subjects are asked to rate the

importance of selected aspects of life functioning. Secondly, the specificity of the influence of variables within these domains on QOL (for example, the finding that contact with non-family members was predictive of life satisfaction while contact with family members was not (Edwards and Klemmack, 1973) provides evidence of the individual nature of QOL. Finally, the limited role that demographic variables play in determining QOL was noted in a number of studies. This is discussed in greater depth in a later section.

## 1.3 CONCEPTUALISATION

While a consensus appears to exist as to the key life domains pertinent to QOL, the way in which a person arrives at a determination of their QOL remains a subject for debate. A number of attempts have been made to conceptualise QOL and these fall into four main types: needs satisfaction/attainment of goals; achievement-aspiration discrepancy; social models and relational models.

### 1.3.a Needs satisfaction/attainment of life goals

Hornquist (1982) proposed that QOL is the "degree of need satisfaction" within six specific areas (physical, psychological, social, occupation, economic status, structural). Once basic survival needs have been met, the determination of needs is an individual phenomena. A complex relationship between the six areas of need is suggested with, assuming that all needs cannot be met, the individual having to make choices (conscious or unconscious) as to which needs to fulfil. This idea contrasts with the need hierarchy proposed by Maslow (1970). Maslow proposed that man is motivated to satisfy needs in a pre-determined order, the higher needs being ignored until the more basic needs are met. The hierarchy suggested is physiological needs, safety needs, social needs, ego needs, status recognition and self-fulfilment. Hornquist (1982) also distinguishes extrinsic (type of housing, signs of appreciation) and intrinsic (satisfaction with housing, experienced self-esteem) needs. Intrinsic satisfaction is influenced by desires as well as extrinsic satisfaction.

A similar approach is outlined by Cohen (1982) who suggests a theory of life quality based on the capacity of an individual to realise his own life plans. This theory is based on the work of the American philosopher Josiah Royce who held that "a human person is a life lived according to a human plan". It is this life plan that gives us our individuality and a purpose to life. Thus, when we describe what we have done, what we are doing and what we intend to do with our lives, we are giving an account of ourselves, justifying our existence. Illness impacts on quality of life by preventing us from following this plan.

### 1.3.b Achievement-Aspiration Discrepancy

Campbell et al. (1976) define satisfaction as the "discrepancy perceived between aspiration and achievement" and advocate the use of this term in defining QOL. Satisfaction is seen as a cognitive process in which a comparison with some external criteria (including expectations) is made. The suggestion of the role of desires and expectations in determining QOL is supported by Staats and Stassen (1987) who argue that future expectations are a major component of present perceived quality of life. Thus, actual abilities or life situation are not as important as the discrepancy between actual situation and expected or desired situation. In addition, Campbell et al. (1976) propose that a differentiation be made between 'satisfaction of success' in which rising expectations and goals are achieved and that associated with declining expectations.

Calman's Gap (Shipper et al., 1990) illustrates the way in which the achievement-aspiration discrepancy has been incorporated into the QOL concept within the medical sphere. Calman (1984) working with cancer patients defines QOL as "the gap between the patients expectations and achievements". It is proposed that the smaller the gap the higher the QOL. Arising from this proposal a number of assumptions are made: 1) the gap may vary over time; 2) expectations set by the patient need to be realistic to avoid frustration and maximise QOL; 3) professionals can temper patient expectations and prepare them for changes and limitations that will occur as disease

progresses. The importance of the achievement-aspiration discrepancy is supported by a number of empirical studies. Bortner and Hultsch (1970), for example, found that "self ratings reflecting opportunities to select goals and access to means for achieving goals were most predictive of life satisfaction". Similarly, Krupinski (1982) found that the prevalence of psychiatric disorder was less related to the individuals objective way of life than to whether or not people achieve their aspirations and concludes that "the perceived fulfilment of their desires had the highest association with their health and well-being".

### 1.3.c Social/relational models

Social/relational models of QOL propose that when an individual is determining their current QOL they make comparisons between their situation and some external criteria, for example, how they have functioned in the past or the perceived abilities/QOL of family, friends and peers.

The World Health Organisation (WHO, 1980) suggest that the impact of disease on an individuals QOL is made by comparison to his or her peer group. They propose three levels at which disease can impact on an individual: impairment, disability and handicap. Impairment refers to abnormalities of body structure and organ/system functioning and thus relates to the impact of disease at the physiological level. Disability is seen as the impact of illness on the persons functional ability and activity level. It is the definition of handicap which most closely relates to quality of life issues. Handicap is defined in societal terms and attempts to define the disadvantage (due to disease or treatment) in which an individual finds themselves in relation to their peers when viewed from the norms of society. Thus handicap in terms of employment would differ for the patient who is beyond retiring age and would not normally be expected to be working and for the younger patient who cannot work due to illness, but would be expected to do so if in good health. The link between degree of disability and handicap is complex. It is possible to be disabled and not be handicapped. The person with a severe disability may well be able to perform all their normal

social roles with the use of physical aids and/or support from professionals, work colleagues, family and friends. Conversely, a minor disability may result in severe handicap dependent upon the situation in which the individual finds themselves. Many factors will influence the degree to which a particular disability will be seen as a handicap including age, sex, attitudes. support and type of society.

The social nature of the QOL concept is also highlighted by Levine and Croog (1984) who state that a major component of QOL is "the ability of an individual to perform his or her social roles and the degree to which enjoyment or satisfaction is derived from performing these roles".

Some evidence to support the relational nature of QOL can be found in a study conducted by Potter and Coshall (1987) in South West Wales. This study examined satisfaction with a number of selected life domains. The authors state that "to understand the QOL experience of individuals it is necessary to understand the situational nature of that experience". It was hypothesised that individuals are intensely concerned with situations that are involved in their daily lives and thus satisfaction would be greater for these domains. For example, it would be expected that satisfaction with home and family would be greater than satisfaction with democracy in Britain. 293 individuals rated 11 domains on a satisfaction scale ranging from 1 (totally dissatisfied) to 7 (completely satisfied). The results were in line with the hypothesis, in that perceived satisfaction with the 11 domains decreased with increasing social complexity. The social complexity of the domains had been pre-determined by the authors. The mean levels of satisfaction were: home (6.20); region (6.02); neighbourhood (5.96); health (5.84); family's education (5.83); leisure time (5.66); job (5.59); standard of living (5.57); religion in Britain (4.05); democracy in Britain (3.88); economic state of Britain (2.95). An alternative explanation, however, may be that individuals have more control over the less socially complex domains and thus can alter their situation to achieve maximum satisfaction.

A proposal by Wood-Dauphne and Williams (1987) focuses on the relational nature of QOL. Reintegration to

normal living is proposed as a proxy for QOL and is defined as "the reorganization of physical, psychological and social characteristics of an individual into a harmonious whole so that one can resume well-adjusted living after an incapacitating illness or trauma". Thus, the aim of the health professions is to enable each patient to resume living life as normally as possible within the constraints of disease. A number of domains within which normative functioning should be targeted are given and these include: mobility, ADL, daily activities, recreational activities, social activities, family roles, personal relationships, presentation of self and general coping skills.

## 1.4 INFLUENCE OF DEMOGRAPHIC VARIABLES ON QOL

An understanding of the influence of common demographic variables on ratings of QOL or life satisfaction is an essential component when interpreting the findings of studies evaluating the QOL of groups of people. The results of between-subject study designs, where for example the QOL of patients with different illnesses or receiving differing treatments is assessed may be influenced by such factors as age, gender, education and occupation of the subjects. The following section attempts to address the following questions: to what extent do different groups of people view life differently?; how do factors such as age, gender and education influence ratings of life satisfaction; do the important components of QOL differ across groups?. Intuition suggests that such differences are likely, but is this backed by scientific evidence? Variables which may be of importance include age, gender, income, social class, education and occupation and these are discussed separately in the following sections.

### 1.4.a Age

It has long been supposed that older people are less happy than younger people (Cameron, 1975) and this was supported in early studies (see Diener, 1984 for review) and by the findings of a study by Edwards and Klemmack (1973) who demonstrated a significant negative correlation between age

and life satisfaction in a group of subjects aged 45 years and over (no upper age limit is specified) suggesting that satisfaction decreases with increasing age. Cameron (1975), however, found no age differences in the frequency of happy or sad moods in a study of 6707 subjects. This study employed a very restricted assessment of life satisfaction, namely mood, on the assumption that affective state is the largest component of any appraisal of life satisfaction and thus may be considered a proxy measure of this concept. Similarly, Palmore and Luikart (1972) found only a low negative correlation between age and life satisfaction, and when a comparison of those aged over and under 60 years of age was made, found no difference in the degree of life satisfaction in the two groups. Subjects in this study were aged 45-69 years of age. No influence of age also was noted by Mor (1987) in a study in which a range of variables were examined in relation to their ability to predict scores on the Quality of Life Index (Spitzer et al., 1981).

In contrast, other studies have reported increasing satisfaction with increasing age. Bortner and Hultsch (1976), for example, report group differences in satisfaction attributable to age. Subjects were classified into 6 age groupings (20-29, 30-39, 40-49, 50-59, 60-69, 70+) and analysis of variance used to test group differences on life satisfaction scores. The mean age of subjects was 45.6 years (SD=15.75). The older age groups reported higher levels of satisfaction. The authors suggest that this factor may mediate life satisfaction through the enhancement of other more subjective aspects involved in QOL, for example, achievement of life goals. A similar finding is reported by Mookherjee (1987) in a survey of 1506 American adults (aged 18-89). Multiple regression analysis indicated that perception of life satisfaction was influenced by age with younger people expressing greater dissatisfaction. It is interesting, however, that this finding was only seen in the better educated group. Potter and Coshall (1987) also report increased satisfaction in older age groups with older people expressing higher levels of satisfaction with a range of life domains.

Age differences have been noted, not only in terms of overall life satisfaction, but also in relation to what aspects of life are important to satisfaction. Krupinski (1982) noted some interesting age differences in relation to the importance of various domains to QOL. Participants were aged 12 to 65+ (no upper age limit specified). 'Family', 'freedom from worries' and 'material security' were considered important by all age groups, although elderly males tended to rate family less highly and freedom from worries more highly than all other age/sex groups. Perception of the importance of 'recreation' and 'working conditions' decreased with increasing age. The importance of 'personal relations' was most highly valued by the very young and the very old. No age differences in the importance given to 'freedom from pressure' was seen, While this study is vague in terms of its definitions (what age does elderly or very old start) it raises the interesting issue that not only may overall life satisfaction be a function of age, but that the life domains important to QOL may also change as a function of age.

Steinkamp and Kelly (1987) found age differences in the role of factors mediating QOL. This study examined the influence of leisure activity on satisfaction in a group of people aged over 40 years of age. The relationship between objective (number of friends, number of visits) and subjective (feelings of loneliness, sense of belonging) social integration and total leisure activity to life satisfaction was investigated. Total leisure activity was associated with life satisfaction in the under 65's, but not in the over 65's. Differences in the role of social integration were also noted. In the under 65's low social integration (both objective and subjective) did not adversely influence feelings of life satisfaction. People in the low objective/low subjective group reported similar degrees of satisfaction as those in high objective/high subjective and high objective/low subjective groups. In the under 65's those reporting low objective/high subjective social integration were the most satisfied. In contrast, degree of social integration was more important in the over 65's. In this age band, the low objective/low subjective group reported lower satisfaction with life than

the other groupings (low objective/high subjective, high objective/low subjective, high objective/high subjective).

A number of theories to explain age differences in life satisfaction have been proposed. Felton (1987) puts forward an interesting theory to account for age differences in well-being. She suggests that the historical circumstances into which an individual is born and brought up shapes their values and belief systems. Differences in these belief systems across generations may explain 'age' differences in life satisfaction. In particular a distinction between those born before and after 1900 is made. Pre-1900 cohorts, it is suggested, base their satisfaction on materialistic or survival issues. In contrast, those born post-1900 have shifted away from materialistic values and base their satisfaction on more 'personal' attributes. This is an interesting proposal and while the existence of 'cohort effect' remains unproven it does highlight the importance of an individuals' belief and value system in the determination of their QOL. Campbell (1981) links age differences to changes in life cycle such as the transition from adolescence to adulthood, from being single to being married, from being a non-parent to a parent and from being a couple to being widowed. Age effects are also often confounded by interactions with other factors such as income and occupational status. Older people are more likely to be at height of their earning potential and to have attained the occupational status desired (Campbell, 1981).

In summary, the relationship between age and life satisfaction or QOL appears to be a complex one. In general, demographic factors have been shown to be poor predictors of QOL (Andrews and Withey, 1976; Campbell et al., 1976), however, Campbell et al. (1976) report that while the overall predictability of demographic factors is low (accounting for only 17% of variance in life satisfaction scores), age was the strongest of the situational variables in predicting life satisfaction.

### 1.4.b Gender

There appear to be surprisingly few gender differences in relation to either life domains important to QOL or overall satisfaction with life. Palmore and Luikart (1972) and Edwards and Klemmack (1973) found no association between gender and ratings of actual life satisfaction. These findings are supported in a review by Diener (1984) of factors influencing subjective well-being, including gender, who concludes that "although women report more negative affect, they also seem to experience greater joys, so that little difference in global happiness or satisfaction is usually found between the sexes". In contrast, Costa et al. (1987) found males scored higher on total well-being than females.

While little difference in overall life satisfaction has been seen, a number of studies have reported gender differences in relation to satisfaction with specific life domains, for example health. Hall (1976) in a British survey of subjective measures of QOL observed that women regarded health as an important component of the quality of their lives more often than men. Okun et al. (1984) conducted a meta-analysis of studies investigating the relationship between subjective health and overall well-being and found a stronger relationship for women than for men. In contrast, a study by Willits and Crider (1988) found no effect of gender on this relationship. Cameron (1975) found that women were more likely than men to report negative emotional states, a finding supported by Briscoe (1982), who in a review of sex differences in well-being, noted that women were more likely to report psychiatric and physical problems than men. This finding is also supported by the work of Campbell (1981) who, in a large survey of the American population between 1957 and 1978, found that women were more likely to describe experiences of negative affect. It has been suggested that women report more symptoms because illness is less stigmatizing for women: 'the ethic of health is masculine' (Phillips, 1964). Alternatively the increased concern about health seen in women may heighten their perception of symptoms (Briscoe, 1982).

With regard to life domains considered important to QOL, Palmore and Luikart (1972) reported gender differences. In women, self-rated health, organisational activity and internal control were the most important correlates of life satisfaction. In contrast, in men, the factors which correlated most highly with life satisfaction were: self-rated health, organisational activity, having a confidante, high performance status (physician's rating of health), amount of employment and social activity. Hall (1976) reported that women regarded family life as important while men were more concerned with their standard of living, work and political freedom. Gender differences in areas of importance were also noted by Krupinski (1980) who used a specifically designed questionnaire in which respondents were asked to rate how important different aspects of life were to them. A randomly selected population of 3105 people (977 households) was surveyed and it was found that women placed higher importance on family, being free of worries, material security, personal relations, being in useful work and freedom from pressure at work than did men. In contrast, men placed higher importance on recreation and housing. In patients with epilepsy, McGuire (1991) observed gender differences in relation to areas of importance to QOL. Areas of importance were elicited through a semi-structured interview and were individual to each patient. Females listed anxiety and keeping in touch with friends more often than did males, while males listed anger, having a partner and lack of social life more often than did females.

Self-image is another area is which gender differences have been seen. Campbell (1981) in study of well-being in the American population found that women were less willing to express satisfaction with themselves as a person and also felt less in control of their lives. In the same study, dissatisfaction with self emerged as more predictive of general well-being that dissatisfaction with any other area studied (which included health, relationships, marriage, society, work and education).

In summary, while subtle differences may exist between the sexes as to the areas of importance to QOL, little

difference in overall life satisfaction is seen and gender is not considered a useful predictor of QOL (Campbell, 1981).

### 1.4.c Income

It is often assumed that higher income inevitably equates with greater life satisfaction. Income, does indeed, play a role in feelings of life satisfaction, but the relationship can be complex as evidenced by the findings of Palmore and Luikart (1972) who found income to have a moderate correlation with life satisfaction, with the association being higher in the low income than the high income group. This finding would be expected from Maslow's needs hierarchy (Maslow, 1955) which suggests basic needs are only of importance until they are met. This could explain differences between high and low income groups. As Palmore and Luikart (1972) state "while it may be true that money can't buy happiness, adequate income may provide more of the basic necessities related to life satisfaction such as adequate food, housing, security, recreation and social status'. Similarly, a role for income is noted by Edwards and Klemmack (1973) who reported that of a range of demographic variables studied, the highest correlation was seen between income and life satisfaction. In addition, Costa et al. (1987) reported increased well-being in higher income groups. It has been suggested that satisfaction with income as opposed to actual income level may be a better predictor of life satisfaction (Campbell, 1981).

The relationship of income to other factors likely to influence QOL has been raised. Campbell (1981) reports an inconsistent relationship between income and life satisfaction. In addition income was found to be positively related to satisfaction with health, education, neighbourhood and housing, but was not related to satisfaction of an interpersonal nature (satisfaction with marriage, family life, friendships, self). The same study reports an interaction between income and education. At low levels of income, the better educated are more satisfied with their lives than those with a lower educational level, while at high levels of income no differences are seen (Campbell, 1981). Similarly, McKenzie and Campbell (1987) found income indirectly affected QOL

measures through mediating factors such as education, perceived health and problems experienced.

In summary, the role of income in determining QOL is modest and often complicated by interaction with mediating factors such as education and perceived health. Thus, while income has some bearing on a person's well-being, there are a number of other influences which come into play in determining an individuals satisfaction with life.

1.4.d **Education**

As with income, the relationship between education and life satisfaction is complex. Palmore and Luikart (1972) found no direct relationship between education and life satisfaction. Similarly, Campbell (1981) and Steinkamp and Kelly (1987) conclude that education is not a useful predictor of life satisfaction.

Some studies, however, have reported a positive association between education and QOL ( Edwards and Klemmack , 1973; Costa et al., 1987; McKenzie and Campbell, 1987; Mookherjee, 1987). In the study by McKenzie and Campbell (1987) life satisfaction increased with educational level. Path analysis suggested that the effect was achieved both directly (direct influence of educational level on life satisfaction scores) and indirectly (through the influence of education on perceived health status and hence life satisfaction). An association between education and physical health was also noted by Campbell (1981). As noted previously, a complex relationship also exists between education and income level exists (Campbell, 1981).

In contrast, higher levels of education have been shown to have a negative effect on life satisfaction (Campbell, 1981). This finding is similar to a study by Bradburn and Caplovitz (1965) who found that when income is adequate, higher education results in a greater discrepancy between ideal and actual achievements. Such unrealistic expectations have a negative influence on QOL.

In summary, educational level does not appear to exert any great influence on QOL. The influence of education may be mediated through such factors as income level and perceived health.

### 1.4.e Occupation

Occupation is related to feelings of social status. People have clear ideas of what are high and low prestige occupations and these are not always related to income. For example, being a minister may be considered a high prestige occupation, but with a low income. Campbell (1981) reported little difference between a variety of occupations in terms of their overall life satisfaction. Similarly, Steinkamp and Kelly (1987) found, in an elderly population, that occupation was not related to feelings of QOL.

Occupation seems to be of most importance to QOL not in relation to type of occupation, but whether or not an individual is employed. Comparing the employed and the unemployed, Campbell (1981) noted that "the absence of an occupation has very substantial implications for feelings of well-being". This study found the unemployed were less likely to be happy or satisfied with their lives, even when income level was statistically controlled for. Similarly, Potter and Coshall (1987) reported lower levels of satisfaction with a variety of domains among the unemployed. The exception to this negative finding for unemployed persons are the retired. This group of people generally exhibit similar levels of satisfaction to the employed (Campbell, 1981).

### 1.4.f Other factors

QOL is a complex phenomenon which may be mediated by a multitude of factors. Other factors which may influence QOL include:

#### 1.4.f.i Demographic

1. Marital status: marital status is generally associated with increased feelings of well-being (Cameron, 1975; Campbell, 1981; Costa et al., 1987; Mookherjee, 1987).
2. Social status: people with higher social status express greater satisfaction with life (Cameron, 1975; Potter and Coshall, 1987).
3. Race: minority status has been associated with lower levels of QOL (Costa et al., 1987; McKenzie and Campbell, 1987).

1.4.f.ii **Personal**

1. Social support: the degree of social support available has been proposed as a mediator of life satisfaction, with the suggestion that individuals with access to high levels of support will experience greater satisfaction with life (Levitt et al., 1987). An issue pertinent to this area is the role of quantitative support (number of support figures, frequency of contact) versus qualitative support (perceived closeness of relationships, feeling of support/security).
2. Activity level/Social integration: Activity Theory has been proposed to explain the degree of perceived life satisfaction, particularly among elderly populations (Havighurst and Albrecht, 1953 quoted in Steinkamp and Kelly, 1987). Studies of the relationship between overall degree of activity and life satisfaction have produced equivocal results (Okun et al., 1984; Reich et al., 1987). This led researchers to investigate more closely the nature of the activity. Characteristics of activity that have been investigated include the degree of social integration necessitated by the activity (objective versus subjective integration, Steinkamp and Kelly, 1987) and whether or not the activity is desired and in the control of the individual (desired activity eg. doing a hobby, watching favourite TV show, playing cards/board games) or arises from the external world and is beyond the individuals control (demand activity eg. car needs repairing, hair needs washing, letters have to be written) (Reich et al., 1987).
3. Personality: a number of personality traits are likely to influence the way an individual perceives their QOL, for example, intelligence, having an optimistic/pessimistic approach to life, feelings of personal control and self-esteem (Diener, 1984). With regard to feelings of personal control, it has been demonstrated that individuals who feel in control of their lives are more satisfied with life (Lewis, 1982; Levitt et al., 1987). In relation to health issues, Lewis (1982) noted a dichotomy between feelings of control over life in

general and feelings of control over health. The former was consistently and positively associated with life satisfaction while the latter produced only inconsistent findings. The concept of personal control is discussed by Lewis (1982) within the theoretical framework of two reinforcement paradigms, namely Rotters' Social Learning Theory (Rotter, 1954, 1966, 1974) and Seligmans Theory of Learned Helplessness (Seligman, 1975).

Self-esteem has been show to be a strong predictor of subjective well-being, with high self-esteem being predictive of increased life satisfaction (Campbell, 1981; Diener, 1984). Campbell (1981) found satisfaction with self showed the highest correlation with life satisfaction of any variable.

No relationship between intelligence and level of satisfaction has been noted. The influence of personality factors on life satisfaction is an area in which further research is needed.

4. Health: health has emerged in a number of studies as an important mediator of QOL (Edwards and Klemmack, 1973; Campbell, 1981; Okun et al., 1984; Levitt et al., 1987). In addition, self-rated health appears to be more predictive of QOL than objective health (Diener, 1984). Questions, however, about the process and causal relationship between health and QOL remain unanswered. Does ill-health directly affect life satisfaction or is the association due to the effects of ill-health on other life domains that are important to life satisfaction, for example, being able to work, reduced activity levels and limited social opportunities?

A discussion of all the potential mediators of QOL is beyond the scope of this thesis. A good review of the factors influencing subjective well-being is given by Diener (1984). It should be noted, however, that subjective well-being (as discussed in this review) incorporates the concepts of happiness and affective state as well as life satisfaction. As discussed previously, 'happiness' is not accepted as a suitable proxy for QOL due to the ephemeral nature of this concept (Goodinson and Singleton, 1989).

### 1.4.g Summary

The impact of demographic variables on QOL appears to be minimal when compared to psychosocial variables, however, some differences have been noted and thus researchers of QOL need to be aware of the potential influence of these variables. Campbell (1976), in an examination of the relationship of the objective circumstances of life to an individuals sense of well-being concludes that "there is a great deal about the way people feel about their lives that cannot be predicted from knowledge about the circumstances in which they live".

## 1.5 SUMMARY AND WORKING DEFINITION

Based on a review of the literature, a working definition of QOL is proposed which forms the basis of the development of a novel method to assess the QOL of patients with epilepsy. A number of attributes of the QOL can be defined and form the basis of a working model of QOL:

1. Multidimensional

QOL is a multidimensional concept influenced by performance in, and satisfaction with, a number of life domains. These can be summarised into 5 broad domains: physical functioning, cognitive functioning, emotional status, social functioning and economic/employment status.

2. Individual

QOL is an individual phenomena in which an individuals beliefs, desires and perceptions play an integral role. A true assessment of an individuals QOL can, therefore, only be given by the individual themselves.

3. Relational

QOL is a relational phenomena in which an individual makes comparisons (conscious or unconscious) between their current life situation and some external criteria (for example, past abilities, peers).

4. Achievement-Aspiration Discrepancy

The discrepancy between actual situation and expectations or aspirations is an important component in the determination of QOL by an individual.

5. Changing phenomenon

QOL is not a static phenomenon. It is in a constant state of flux, with changes being related both to objective circumstances (for example, deteriorating physical health) and subjective perceptions (for example, changing expectations).

# CHAPTER 2
# EPILEPSY

## 2.1 HISTORY

The sacred disease, an ancient name for epilepsy, is probably the oldest known disorder of the brain. As early as 2080 BC it was mentioned in the ancient Babylonian law of Hammurabi (Scott, 1973). The terminology 'the sacred disease' probably arose as a consequence of the belief that epilepsy was an illness inflicted by the gods. The thread of superstitious belief runs throughout the history of epilepsy. Not only has it been viewed as an infliction from the gods, but it has also been associated with possession by demons or evil spirits and as a punishment from Selene, the goddess of the moon (Temkin, 1948, p6).

The first reference to epilepsy as a disease with natural causes is to be found in a monograph entitled 'On the Sacred Disease' which is part of the Hippocratic collection of medical writings and dates from the year 400 BC. This treatise, written for the lay person, was aimed at dispelling the popular myths that surrounded epilepsy at that time. It proposes a theory of the aetiology of epilepsy which contains four main components. First, epilepsy is held to be a natural disease; second, like other diseases, it is hereditary; third, the seat of the cause of the disease lies in the brain; fourth, a humoral principle is proposed to explain the illness. The humoral theory, based on the four humors of blood, phlegm, black bile and yellow bile, was (with a few minor variations) generally accepted by subsequent physicians and philosophers. Galen, 500 years after Hippocrates systematised and expanded the humoral theory to include the four qualities of cold, warm, moist and dry. Galen believed (as did Hippocrates) that epilepsy originated in the brain and that it was due to an obstruction caused by the agglomeration of a thick humor in the middle or posterior ventricles of the brain. This blocked the passage of the psychic pneuma (which, through the spinal cord and nerves, accepted sensations and carries commands to the voluntary muscles). Convulsions were the body's way of ridding itself of the blockage. He further

postulated that the humor could be either phlegmatic (cold and moist) or melancholic (cold and dry) (Temkin, 1948).

The Dark and Middle Ages saw a regression back towards a non-scientific approach to epilepsy. Little differentiation was made between epilepsy and other 'falling evils', for example, periodic ecstasies and raptures. Epilepsy became increasingly associated with possession, this idea being substantiated by Christian beliefs and writings about the miracles of Jesus (Hill, 1981). It was also during this period that the link between epilepsy and the moon was strengthened. The term 'lunatic' was used to describe people suffering from abnormal states that were regular and periodic attacks, including those suffering from epilepsy (Temkin, 1948, p90). The idea of epilepsy as a contagious disease can be traced back to the ancients, and during medieval times this view persisted. It was only in the 16th century, a time which saw increasing knowledge about contagious diseases, that the contagious aspect of epilepsy was refuted by physicians. The medical theories of the medieval ages saw little advance on those proposed by Galen. Temkin (1948) does however pay tribute to the physicians of this time for keeping alive the tradition of epilepsy as a natural disease.

The Renaissance period and onwards saw a broadening of clinical knowledge of epilepsy and a weakening of the superstitious beliefs, although there is some evidence to suggest their existence as late as the 20th century (Temkin, 1948, p210). One of the many theories to emerge at this time was the irritation theory of epilepsy. This theory, while partly based on the work of Galen, was first described by Fernelius [1485-1558] and sees cerebral irritation as the cause of epilepsy. This view was challenged by Willis [1621-1675] and Boerhaave [1668-1738], who both viewed epilepsy from a more scientific and clinical viewpoint, seeing it simply as a physical consequence of pathological processes (Bunker, 1948). In the 19th century a divergence of views started to be seen in the psychiatric and neurological fields. Psychiatrists, generally dealing with the most resistant cases, saw epilepsy in global terms proposing a 'degeneracy

theory' where the disease was the result of a progressive hereditary degenerative strain. In contrast, neurologists were interested in a physiological understanding of the nervous system and the relationships between seizures and brain pathology (Hill, 1981).

In more recent times, Russell Reynolds (1861) was the first to acknowledge and define 'idiopathic epilepsy', while Hughlings Jackson (Jackson, 1870; Jackson, 1873; Jackson, 1890) in his writings on paroxysmal disorders produced the first scientifically accurate description of epilepsy: 'an occasional, sudden, excessive, rapid and local discharge of grey matter'. Gowers (Gowers, 1881; Gowers, 1907) and Lennox (Lennox, 1941; Lennox and Lennox, 1960) also deserve a mention for their contributions to the study of epilepsy. The 20th century has seen many advances in the our knowledge of epilepsy, including innovations in treatment and diagnoses. Undoubtedly one of the major contributors was the introduction of the EEG in 1929 by Hans Berger. Other major innovations include the introduction of phenobarbitone in 1912 and phenytoin in 1937 (Bunker, 1948).

## 2.2 DEFINITION AND CLASSIFICATION

### 2.2.a Definition

The words 'epilepsy' and 'epileptic' are of Greek origin having the same root verb 'epilambanein' which means 'to seize' or 'to attack'. 'Epilepsy' therefore, means 'seizure'; 'epileptic' 'seized'.

Modern definitions of epilepsy, however, are more complex than this simple, semantic approach would suggest. Definitions of epilepsy vary, as can be seen in Table 2.1, yet several common themes are apparent. First, a distinction is made between the term 'seizure' and 'epilepsy'. A good example of this is given in the clear definitions of these terms made in the epidemiological study of Hauser and Kurland (1975). They define a seizure as 'the clinical manifestation of paroxysmal neuronal hyperactivity in the brain which may appear as an abrupt change in the state of consciousness, an alteration in the persons perception of the environment, or an involuntary response to the environment', while 'epilepsy' is defined as

'a condition in which seizures recur chronically without pronounced, noteworthy provoking factors, because of a persistent and possibly progressive structural or physiological abnormality of the brain tissue'.

Table 2.1 : Selection of definitions of epilepsy

| |
|---|
| A chronic brain disorder of various etiologies characterised by recurrent seizures due to excessive discharge of cerebral neurones (epileptic seizures) associated with a variety of clinical and laboratory manifestations.<br>(Gastaut, 1973) |
| Epilepsy is defined as a condition in which seizures recur chronically without pronounced, noteworthy provoking factors because of a persistent and possibly progressive structural or physiological abnormality of brain tissue.<br>(Hauser and Kurland, 1975) |
| Epilepsy is a collective term for a group of chronic disorders of the central nervous system having as their common symptom the occurrence of seizures.<br>(Thompson, 1981) |
| The fits are paroxysms and recurrent and the symptoms of the fit are the result of excessive cerebral activity, but the illness epilepsy is more than just the fit.<br>(Marsden and Reynolds, 1982) |

Secondly, in the majority of definitions, seizures are seen as a clinical manifestation of abnormal cerebral activity. This link follows on from Hughlings Jacksons classic description of seizure activity given above. Thirdly, it is generally agreed that the cardinal feature of epilepsy is the recurrence of seizures (Marsden and Reynolds, 1982). Finally, the diverse nature of the disease is acknowledged. This diversity, in terms of clinical presentation, EEG patterns and aetiology has been noted since ancient times. Aretaeus in the 2nd century is reported to have said "Epilepsy is a illness of various shapes and horrible." (Temkin, p35).

2.2.b **Classification**

There is a need for a common classification system, both for accurate diagnosis and treatment, and for greater communication between professionals working within the field of epilepsy. The International League Against Epilepsy, recognising this need established a Commission on Classification and Terminology, which published its first scheme of classification in 1964. This was followed in 1969 by a revised scheme (Gastaut, 1969), based on descriptions of seizure type, electroencephalographic seizure type, electroencephalographic interictal expression, anatomical substrate, aetiology and age. The main feature of the 1969 classification was the distinction between seizures that are generalised from the outset and those that are partial/focal at onset, but may later become secondarily generalised.

This classification was widely used for a number of years, only being revised in 1981 (See Table 2.2). There are two distinct differences between the 1969 and the 1981 classification. First, the 1981 scheme is based on clinical seizure type, EEG seizure type and inter-ictal EEG expression only. The description of anatomical substrate, aetiology and age factors were excluded as it was felt that these were based on historic or speculative information and could not be directly observed. Second, in the 1981 classification a distinction is made between simple partial seizures, in which consciousness is not impaired, and complex partial seizures, in which consciousness is impaired.

Table 2.2: Commission on Classification and Terminology of the International League Against Epilepsy: Clinical and Electroencephalographic Classification of Seizures (1981).

I. PARTIAL (FOCAL/LOCAL) SEIZURES

A. Simple partial seizures (consciousness not impaired)
   1. With motor signs
   2. With somatosensory symptoms (simple hallucinations eg tingling, flashing lights)
   3. With autonomic symptoms or signs (including epigastric sensation,pallor, flushing, piloerection and pupillary dilation)
   4. With psychic symptoms (disturbance of higher cerebral function).

B. Complex partial seizures (with impairment of consciousness)
   1. Simple partial onset followed by impairment of consciousness
   2. With impairment of consciousness at onset

C. Partial seizures evolving to secondarily generalised seizures
   1. Simple partial seizures evolving to generalised seizures
   2. Complex partial seizures evolving to generalised seizures
   3. Simple partial seizures evolving to complex partial seizures evolving to generalised seizures

II. GENERALISED SEIZURES (CONVULSIVE OR NONCONVULSIVE)

A. 1. Absence seizures
   2. Atypical absence
B. Myoclonic seizures
C. Clonic seizures
D. Tonic seizures
E. Tonic-clonic seizures
F. Atonic seizures

III. UNCLASSIFIED EPILEPTIC SEIZURES

includes all seizures that cannot be classified because of inadequate or incomplete data and some that defy classification into hitherto described categories

Partial seizures are those in which the first clinical and EEG changes indicate initial activation of a system of neurones limited to part of one cerebral hemisphere (ILAE, 1981). Simple partial seizures, in which consciousness is unimpaired, may take a variety of forms. They may be accompanied by motor signs (head turning, tonic deviation of eyes); somatosensory symptoms (simple hallucinations, tingling, flashing lights), autonomic symptoms, psychic symptoms (dysphasia, deja-vu phenomena, dreamy states, fears, illusions). Complex partial seizures are distinguished from simple partial seizures in that consciousness is impaired. They may evolve from simple partial seizures, or impairment of consciousness may be present from the start. Complex partial seizures may be accompanied by olfactory or gustatory hallucinations in association with a dreamy state of altered consciousness. Distortions of memory and automatisms may also occur. Automatisms are defined as a continuation of an activity that was going on when the seizure occurred or a new activity developed in association with the ictal impairment of consciousness. Both simple and complex partial seizures may spread to become secondarily generalised. They may generalise with such rapidity that clinically they appear to be generalised from the start.

Generalised seizures are those in which the first clinical changes indicate initial involvement of both hemispheres. Paroxysmal discharges seen in the EEG are bilateral and synchronous from the start. They may be convulsive or non-convulsive. Absence seizures are a non-convulsive type of generalised seizure and can be simple or complex. Simple absence seizures are the classic form of petit mal and are characterised by a brief stare and eyeblinking, generally associated by 3 cps spike-and-wave discharges in the EEG. Complex absence seizures involve a brief loss of consciousness accompanied by addition phenomena, for example, mild clonic movements, brief automatisms or autonomic phenomena. These type of seizures are differentiated from complex partial seizures (in which automatisms can also occur) in that they are of a brief duration (usually 15-30 seconds)

and the EEG pattern which shows symmetrical 2-3 hz spike-and-wave discharges.

The classic convulsive generalised seizure is the tonic-clonic or grand mal seizure and is easily recognisable. An initial and sudden loss of consciousness, often accompanied by a cry, is followed by a clonic phase, which is replaced by a tonic phase. Incontinence and tongue biting may occur. Following the attack there is generally post-ictal confusion and drowsiness. Convulsive generalised seizures may take a variety of other forms including a tonic or clonic phase alone, myoclonic (brief muscle jerks) movements or loss of muscle tone (atonic or drop attacks).

A number of other terms warrant a mention here. Status epilepticus is the term used to refer to seizures which occur in rapid succession, not allowing sufficient time between attacks for a normal state of brain function to be resumed. A distinction between convulsive (tonic-clonic), non-convulsive (complex partial status, absence status), and epilepsia partialis continua can be made. Convulsive status epilepticus is a medical emergency and requires immediate treatment. Febrile seizures are convulsions which are associated with a body temperature greater than 38°C. A classic febrile seizure is a generalised tonic-clonic seizure lasting less than 5 minutes. These types of seizure are commonest in children, and do not necessarily result in a continuing seizure disorder. Reflex epilepsy refers to seizures which are precipitated by specific stimuli, for example, flashing lights, television, reading, performing arithmetic calculations or eating (Solomon et al., 1983). The term pseudoseizure is used to describe any non-epileptic event that resembles an epileptic seizure (Engel, 1989).

## 2.3 EPIDEMIOLOGY

Epidemiological study provides information about the frequency and distribution of disabilities, diseases and deaths and also deals with factors causing the disease or influencing their natural history (Zielinski, 1982). Two measurements commonly used in epidemiological studies are incidence and prevalence. Incidence is a measure of the rate of occurrence of new cases

of a given disease per unit time, within a specified population. The numerator is the number of new cases and the denominator is the number of persons at risk of acquiring the disease, but in practice the total population is often used. In epilepsy, this is normally calculated as rate per 100,000.

$$\text{Incidence} = \frac{\text{number of new cases within a given period}}{\text{population at the middle of the period}} \times 100{,}000$$

Prevalence is defined as the proportion of a population with a given disease at a specified time. The numerator is all cases of the disease, new and old, and the denominator is the total population from which the cases are drawn. Prevalence is normally calculated as rate per 1000 of population.

$$\text{Prevalence} = \frac{\text{number of patients with epilepsy in the population at any given time}}{\text{total population}} \times 1000$$

'Lifetime prevalence' is the number of people within a population who have ever suffered from epilepsy.

Reports of incidence and prevalence rates in the literature vary widely. Much of the variation can be explained by differences in research methods, diagnoses and definition of epilepsy/seizures and case ascertainment and data collection methods. Neugebauer and Susser (1979) estimated that including febrile seizures can inflate incidence and prevalence rates by up to 37 times. Sander and Shorvon (1987), in a review of epidemiological methodology, highlighted several factors which can influence prevalence and incidence rates and which need to be carefully described in epidemiological studies. These include sex, age, seizure type and socioeconomic status. Male sex has been associated with higher rates of epilepsy in several studies, although the reason for this is unclear. It has been suggested that an increased rate of head injury in males may play a role, yet the evidence for this is scanty. Age is also an important factor and the authors suggest that age-specific rates may be more useful measures than overall rates. Prevalence rates increase with age, as expected in a chronic condition such as epilepsy. The review by Sander and Shorvon (1987) also demonstrates that age-specific incidence rates show remarkably

similar trends across studies. Generally, the highest incidence rate is seen in the first decade of life. With regard to seizure type, many of the studies reviewed show a preponderance of generalised seizures. This, Sander and Shorvon (1987) suggest, may be an artefact due to the misclassification of partial seizures which rapidly become secondary generalised. Sander and Shorvon (1987) also highlight geographic variations as an important factor in differences in published prevalence and incidence rates. An example of this is the higher rates reported in the tropics, which are related to the greater incidence of parasitic disorders seen in these countries. The role of socioeconomic status, particularly in relation to access to perinatal care was also noted in this review.

### 2.3.a Incidence rate studies

Incidence rates can only be derived from longitudinal studies and therefore, there are fewer reports of these in the epidemiological literature. Table 2.3 summarises a selection of studies which report incidence rates. While there is a great variation in the rates reported, from 11 to 82 per 100,000, in the majority of studies the rate lies between 20 and 50 per 100,000 (Zielinsky, 1982). One of the earliest, yet most comprehensive studies of incidence (and prevalence) of epilepsy was carried out by Hauser and Kurland (1975) in Rochester, Minnesota (population 55,000). All available records of residents where a diagnosis of epilepsy was made between 1936 and 1967 were retrieved and reviewed. 2900 cases of possible epilepsy were identified, 1448 being accepted as definite cases. They found a mean incidence rate (for the 32 year period) of 48.7 per 100,000. Another comprehensive study by Gudmundsson (1966) of the incidence and prevalence of epilepsy in Iceland reports a mean incidence rate of 25.9 per 100,000. This study included only active cases of epilepsy, defined as having a seizure or taking antiepileptic medication in the previous 5 years. Febrile convulsions were excluded from the analysis. de Graaf (1974) in a review of in- and out-patient records of a neurology department found an incidence rate of 32.8 per 100,000. The rate was highest in the first

Table 2.3: Selected studies of the incidence rate of epilepsy.

| Author(s) | Date | Country | Incidence (per 100,000) |
|---|---|---|---|
| Kurland | 1959 | Rochester | 29.8 |
| Crombie et al | 1960 | UK | 63 |
| Pond et al | 1960 | UK | 70 |
| Krohn | 1961 | Norway | 11 |
| Sato | 1964 | Japan | 17 |
| Gudmundsson | 1966 | Iceland | 25.9 |
| Brewis et al | 1966 | UK | 30 |
| Mathai et al | 1968 | Mariana Islands | 30 |
| Stanhope et al | 1972 | Mariana Islands | 46 |
| de Graaf | 1974 | Norway | 32.8 |
| Zielinski | 1974 | Poland | 20 |
| Hauser and Kurland | 1975 | Rochester | 48.7 |
| Blom et al | 1978 | Sweden | 82 |
| Cavazutti | 1980 | Italy | 82 |
| Juul-Jensen & Foldspang | 1983 | Aarhus, Denmark | 34 |
| Granieri et al | 1983 | Italy | 33 |
| Li et al | 1985 | China | 25 |
| Joensen | 1986 | Faroes | 42 |
| Keranen et al | 1989 | Finland | 24 |

two decades of life, declining thereafter. In addition, a higher incidence rate was noted for males than females.

More recently, Juul-Jensen and Foldspang (1983) identified 1870 patients with a possible diagnosis of epilepsy in Aarhus, Denmark (population 224,800). 365 with febrile convulsions were excluded giving incidence rates of 39 per 100,000 (males) and 28 per 100,000 (females). The highest incidence rate was seen in the 0-9 age group for both sexes. Li et al (1985) conducted a door-to-door survey based on a random sample of households in six cities in China. The total population of the cities was 63,195. An incidence rate of 35 per 100,000 was reported. Again, a higher prevalence rate amongst males was seen. Joensen (1986) performed an 11-year retrospective study in the Faroe Islands and reported an annual incidence rate of 42 per 100,000. The highest rate was seen in the first year of life. Keranen et al (1989) conducted a retrospective survey of epilepsy cases in Finland, with re-examination of the majority of suspected cases. An incidence rate of 24 per 100,000 was reported.

### 2.3.b Prevalence rate studies

As with incidence rates, reports of prevalence rates vary enormously. Table 2.4 summarises a selection of studies of prevalence rates in epilepsy. Reported prevalence rates range from 1.5 to 31 per 1000. It has, however, been noted that in 50% of studies the rate lies between 4 and 10 per 1000 (Zielinsky, 1982). Prevalence rates may be determined from cross-sectional surveys, which accounts for the preponderance of studies reporting prevalence rates. Gudmundsson (1966) reported an incidence of 3.4 per 1000 on December 31st 1964, and a 'lifetime' prevalence of 5.2 per 1000. This is lower than the prevalence of active cases of epilepsy (5.7/1000) reported by Hauser and Kurland (1975).

de Graaf (1974) found a prevalence rate of 3.5 per 1000 in a population in Norway, which is a similar finding to the survey by Hopkins and Scambler (1977) of 17 GP surgeries in London, who found a prevalence rate of 3.5 per 1000. Another UK based study by Goodridge and Shorvon (1983) of 6000 patients in a single general practice, identified 122 patients

Table 2.4: Selected studies of prevalence rate of epilepsy.

| Author(s) | Date | Country | Prevalence (per 1000) |
|---|---|---|---|
| Kurland | 1959 | Rochester | 3.7 |
| Crombie et al | 1960 | UK | 4.2 |
| Pond et al | 1960 | UK | 6.2 |
| Krohn | 1961 | Norway | 2.3 |
| Bird | 1962 | South Africa | 3.7 |
| Sato | 1964 | Japan | 1.5 |
| Jilek-Aall | 1965 | Tanzania | 20.0 |
| Gudmundsson | 1966 | Iceland | 3.4 |
| Brewis et al | 1966 | UK | 6.0 |
| Wajsbort et al | 1967 | Israel | 2.3 |
| Liebowitz & Alter | 1968 | Israel | 4.0 |
| Mathai et al | 1968 | Mariana Islands | 3.4 |
| Stanhope et al | 1972 | Mariana Islands | 5.3 |
| Rose et al | 1973 | USA | 18.6 |
| de Graaf | 1974 | Norway | 3.5 |
| Zielinski | 1974 | Poland | 8.0 |
| Hauser and Kurland | 1975 | Rochester | 5.7 |
| Hopkins & Scambler | 1977 | UK | 3.4 |
| Baumann et al | 1978 | USA | 5.7 |
| Gomes et al | 1978 | Colombia | 19.5 |
| Chiofalo et al | 1979 | Chile | 31.0 |
| Cavazutti | 1980 | Italy | 4.4 |
| Goodridge & Shorvon | 1983 | UK | 20.0 |
| Juul-Jensen & Foldspang | 1983 | Aarhus, Denmark | 12.7 |
| Wagner | 1983 | Copenhagen | 4.3 |
| Granieri et al | 1983 | Italy | 6.2 |
| Tsuboi | 1984 | Japan | 9.0 |
| Li et al | 1985 | China | 4.6 |
| Joensen | 1986 | Faroes | 7.6 |
| Sridharan et al. | 1986 | Benghazi, Libya | 2.3 |
| Haerer et al. | 1986 | Mississippi | 6.8 |
| Marino et al. | 1986 | S. Paolo | 11.9 |
| Keranen et al. | 1989 | Finland | 3.1 |
| Cornaggio et al. | 1990 | Lombardy, Italy | 4.7 |

with non-febrile seizures. A life-time prevalence of 5.3 per 1000 was noted for cases with active epilepsy. A higher prevalence rate of 12.7 per 1000 was reported by Juul-Jensen and Foldspang (1983) in Aarhus, Denmark. In contrast, Wagner (1983) reported an age-specific prevalence of 4.3 per 1000 in Copenhagen. Joensen (1986) reported a prevalence rate of 7.6 per 1000 for all seizure types. Sridharan et al. (1986) in Benghazi, Libya report a prevalence rate of 2.3 per 1000 for cases with active epilepsy (defined as the occurrence of a seizure in the last 3 years or currently taking antiepileptic medication). In Copiah County, Mississipi, Haerer et al (1986) found an active epilepsy prevalence rate of 6.8 per 1000 , with a lifetime prevalence of 10.4 per 1000. Higher prevalence rates were noted for the non-white population and amongst males. Marino et al (1986) in Sao Paulo surveyed 2011 houses in a house-to-house survey, identifying 388 possible cases of epilepsy of which 348 were examined. 91 had a diagnosis of epilepsy confirmed. More recently, Keranen et al. (1989) reported a prevalence rate for 'active' epilepsy of 6.3 per 1000. Cornaggio et al (1990) in a highly selected population of army draftees report a prevalence rate of 4.7 per 1000.

## 2.4 AETIOLOGY

It is clinically useful to distinguish between epilepsies which are 'idiopathic', that is, of no known origin and those which are 'symptomatic', that is, a known cause can be identified. Another term widely used is 'cryptogenic' epilepsy. This term refers to epilepsies for whom the cause is hidden. They are considered symptomatic, but the aetiology has yet to be defined. This distinction is one of the bases of the Revised Classification of Epilepsies and Epileptic Syndromes (ILAE, 1989) - the other being separation of generalised and partial epilepsies. The determination of aetiological factors is of practical
significance so that known causes of seizures, which may be amenable to medical intervention, are treated.

An aetiology for a seizure disorder can generally be established in approximately 1/3 of cases (Shorvon and Farmer,

1988). In their classic epidemiological study, Hauser and Kurland (1975) report that in 75% of the cases studied no known cause for the epilepsy could be identified. Similar figures are to be found in more recent studies. Goodridge and Shorvon (1983) report that of 122 of patients in a GP practice who had a definite diagnosis of epilepsy, no known cause could be found in 91 (74.6%). Similarly, Sridharan et al. (1986) and Li et al (1985) report figures of 82.5% and 79% respectively.

It has been noted that figures for known aetiology in epidemiological surveys depend to some extent on the extensiveness of the investigations made (Sander and Shorvon, 1987). It is likely that advances in technology, for example, neuroimaging techniques will lead to an increase in the number of patients with epilepsy for whom an identifiable cause can be found for their disorder.

There are a number of known causes of seizures and their importance depends to a large extent on the age at which the seizure disorder starts. Table 2.5 summarises known aetiological factors by age of onset of epilepsy. In adults the commonest causes of fits are head injury, brain tumour, cerebral abscess and cerebrovascular disease. Gudmundsson (1966) in an epidemiological survey of epilepsy in Iceland found birth injury to be the commonest cause of epilepsy (38.4%). Following this the commonest causes were head injury (22.7%), encephalopathy/meningitis (14.1%) and cerebrovascular lesions (10.2%). Tumours only accounted for 2% of the cases of known aetiology. These findings have been replicated by other studies (de Graaf, 1974; Goodridge and Shorvon, 1983; Li et al;, 1985; Haerer et al., 1986; Cornaggio et al;, 1990).

### 2.4.a Head injury

Head injury is one of the commonest causes of epilepsy in adults. Seizures occur within 2 years of trauma in 5% of cases of severe closed head injury. This figures rises to 30-50% of cases of open head injuries (Solomon et al., 1983). Seizures are most likely to occur within 1 year of the trauma. Risk factors for the occurrence of late seizures include a depressed skull fracture, the presence of an acute

Table 2.5: Causes of epilepsy, categorised by age of onset of seizure disorder

| NEONATAL (FIRST MONTH) |
|---|
| Birth injury: anoxia, haemorrhage<br>Congential abnormalities<br>Metabolic disorders: hypoglycaemia, hypocalcaemia<br>Cerebral infection - meningitis, abscess, encephalitis |
| INFANCY (1-6 MONTHS) |
| As above<br>Infantile spasms |
| EARLY CHILDHOOD (6 MONTHS TO 3 YEARS) |
| Febrile fits<br>Birth injury<br>Infection<br>Trauma<br>Poisons and metabolic disorders<br>Cerebral degenerations |
| CHILDHOOD AND ADOLESCENCE |
| Idiopathic epilepsy (? genetic propensity)<br>Birth injury<br>Trauma<br>Infection<br>Cerebral degenerations |
| EARLY ADULT LIFE |
| Trauma<br>Tumour<br>Idiopathic epilepsy<br>Birth injury<br>Infection<br>Cerebral degenerations |
| LATE ADULT LIFE |
| Vascular disease: infarction, hypertensive encephalopathy<br>Trauma<br>Tumour<br>Cerebral degenerations e.g. Alzheimer's disease |

Source: Marsden and Reynolds (1982)

intracerebral haemotoma, post-traumatic amnesia lasting more than 24 hours and the presence of dural tears or focal neurological signs. Prophylactic treatment with antiepileptic drugs, particulary where risk factors are present, is often advocated, although much debate remains as to its value in milder cases of trauma.

2.4.b **Cerebral infection/abscess**

Infections of the central nervous system may in themselves produce seizures and, in addition, can cause damage to brain tissue resulting in future seizure foci. Meningitis, particularly occurring between the ages of 6 months and 5 years is recognised as a cause for epilepsy (Solomon et al., 1983). In Third World countries the high incidence of parasitic diseases (toxoplasmosis, cysticerosis) are viewed as a cause for higher rates of epilepsy (Shorvon and Farmer, 1986). Epilepsy is also a common complication of brain abscess (Marsden and Reynolds, 1982). Neurosurgery for the removal of cortical brain abscess is also noted to increase the risk of seizures (Solomon et al., 1983).

2.4.c **Cerebrovascular disease**

In older patients (>50 years), arteriosclerotic cerebrovascular disease is the commonest likely cause of seizures, with the majority of patients experiencing elementary motor or partial seizures with secondary generalisation. In 4% of patients with brain infarction and 10% of patients with intracerebral haemorrhage, seizures will accompany the stroke (Solomon et al., 1983).

2.4.d **Brain tumour**

Brain tumours are responsible for approximately 10% of cases of adult-onset epilepsy, although the incidence is higher for partial fits, where between 30 and 40% of cases may be a result of tumours (Marsden and Reynolds, 1982). In 40% of patients where tumour is the cause, seizures are the first presenting symptom (Penfield and Jasper, 1954).
Removal of the tumour can alleviate seizures in 50% of patients. Temporal lobe tumours tend to produce complex

partial seizures; frontal lobe tumours are more often associated with generalised seizures and a high incidence of status epilepticus; occipital lobe tumours rarely result in seizures.

Another causative factor which bears mention is alcohol and drug withdrawal. It is well recognised that generalised tonic-clonic seizures can develop as the result of the withdrawal or reduction of alcohol or barbiturates. Partial seizures are rarely seen in withdrawal states (Solomon et al., 1983).

## 2.5 TREATMENT

The objective of treatment for epilepsy is to maximise the useful functional capacity of the patient (Engel, 1989). In the majority of cases treatment of epilepsy is by pharmacological means. Table 2.6 outlines some therapeutic parameters for antiepileptic drugs in current use.

### 2.5.a Serum concentration monitoring

One of the major advances of the 20th century in the treatment of patients with epilepsy has been the introduction of techniques for the measurement of serum concentrations of antiepileptic drugs. This is an effective way of monitoring drug activity and is also of value in determining antiepileptic drug (AED) interactions (Engel, 1989).

A therapeutic range of serum level values has been determined for a number, though by no means all, of the first-line AEDs currently in use (Eadie and Tyrer, 1989). Table 2.7 lists the therapeutic ranges of some of the most commonly used AEDs.

These ranges are useful clinically, for example, the upper limit provides a guide to possible toxicity and also acts as an indication of the likelihood of a further response to treatment. They should, however, be regarded as guidelines, not definitive limits and care needs to be taken to ensure that it is the patient and not the serum concentration that is treated (Shorvon, 1987).

Table 2.6: Therapeutic aspects of some commonly used AEDs

| Drug (and ILAE abbreviation) | Trade names (UK & US) | First line indication | Adult oral maintenance (mg/day) |
|---|---|---|---|
| Carbamazepine (CBZ) | Tegretol | Tonic-clonic, partial, tonic | 400-1800 |
| Clobazam | Frisium | - | 10-30 |
| Clonazepam (CZP) | Rivotril/ Clonopin | Myoclonic, atonic | 1-10 |
| Ethosuximide (ETH) | Zarontin/ Emeside | Absence, atonic | 500-1500 |
| Phenobarbitone (PB) | Luminal/ Eskabarb/ Gardenal | Tonic-clonic, partial, tonic | 60-180 |
| Phenytoin (PHT) | Epanutin/ Dilantin | Tonic-clonic, partial, tonic | 200-500 |
| Primidone (PRM) | Mysoline/ Midone | Tonic-clonic, partial, tonic | 250-1000 |
| Valproate (VPA) | Epilim/ Depakine/ Depomide | Tonic-clonic, absence, myoclonic, atonic | 600-2500 |

Table 2.7: Therapeutic ranges of commonly used AEDs

| Drug | Therapeutic range mg/l | μmol/l |
|---|---|---|
| Carbamazepine | 6-12 | 25-50 |
| Clonazepam | 0.025-0.075 | 0.08-0.24 |
| Ethosuximide | 40-100 | 300-700 |
| Phenobarbitone | 10-30 | 45-130 |
| Phenytoin | 10-20 | 40-80 |
| Primidone | As for phenobarbitone | |
| Valproate | 50-100 | 300-600 |

## 2.5.b Pharmacological treatment for epilepsy

Particular types of seizures respond to particular anticonvulsant drugs (Eadie and Tyrer, 1989). A summary of the drugs of first-choice for various seizure types is given in Table 2.8. It is of interest that partial seizures respond to the same drugs used for generalised tonic-clonic seizures. Porter (1982) suggests that this coincidence may reflect the focal origin of many generalised attacks.

The following section will outline briefly each of the mainline antiepileptic drugs currently in use, including date of introduction, applications and side effects.

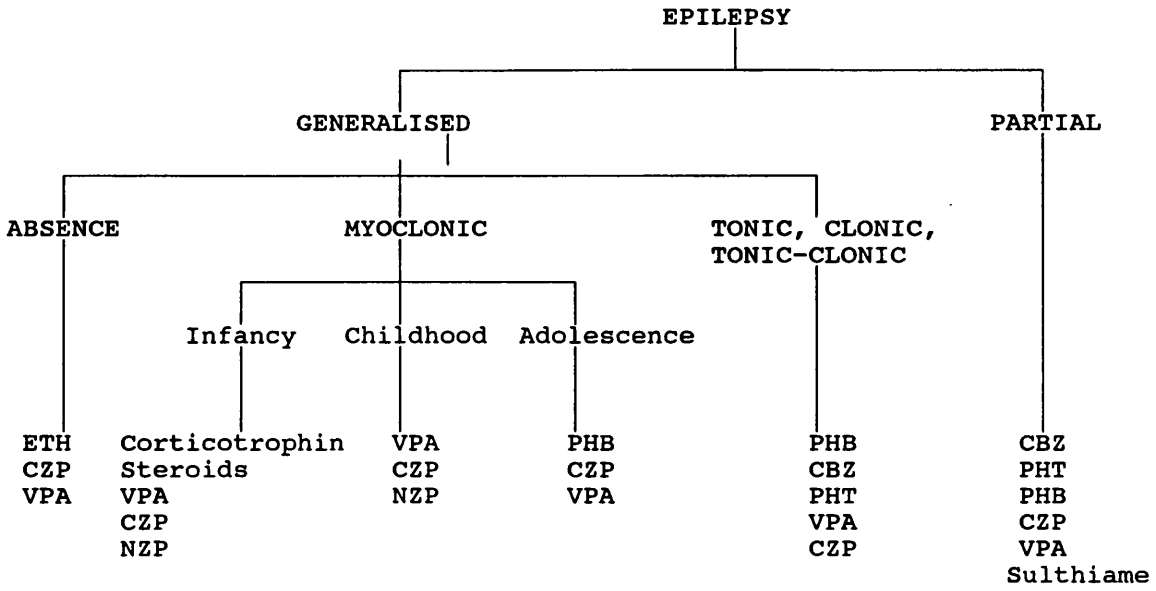
### 2.5.b.i **Bromides**

The introduction by Locock in 1857 of bromide to treat catamenial seizures marked the first rational use of drugs to treat epilepsy. Its use as an antiepileptic agent has been superseded by subsequent drugs (phenobarbitone, 1912; phenytoin, 1938), mainly due to the low ratio between therapeutically effective dose and toxicity (Woodbury and Pippenger, 1982).

### 2.5.b.ii **Phenobarbitone**

This barbiturate drug was first introduced in 1912 by Hauptmann (Eadie and Tyrer, 1989). It is effective for the majority of seizure types, the only exception being generalised absence seizures. Nearly 80 years after its introduction it is still considered a first-line drug for the treatment of tonic-clonic and clonic seizures (Shorvon, 1987). Intravenous phenobarbitone is one of the standard treatments for status epilepticus. It has a slower onset of action than diazepam, but provides a longer period of protection due to its slower elimination profile (Mattson, 1983). While phenobarbitone remains a relatively safe and inexpensive drug, with a similar degree of efficacy to many of the newer AED compounds, it does possess a number of drawbacks which limit its use in routine clinical practice. These include sedation (particularly in adults), disturbances of cognition and behaviour (hyperkinetic syndrome in children), the occurrence of withdrawal syndromes and the danger of overdose.

Table 2.8: Antiepileptic drugs of choice by seizure type




Source: Eadie and Tyrer, 1989

2.5.b.iii **Phenytoin**

This drug, one of the hydantoin group of drugs, was first synthesised by Blitz in 1908, although its anticonvulsant properties were only recognised in 1938 by Merritt and Putman (Eadie and Tyrer, 1989). It is a drug of first choice for the treatment of tonic-clonic and partial (simple and complex) seizures. Tonic and atonic seizures may also respond to treatment with PHT (Browne and Pinus, 1983). In addition, intravenous PHT therapy is effective in status epilepticus (Engel, 1989). Common dose-related toxic side-effects include ataxia, dizziness, nystagmus, diplopia and tremor.

2.5.b.iv **Primidone**

This drug was synthesised in 1949 and came into routine clinical use in 1952 following a report by Handley and Stewart (1952) (Eadie and Tyrer, 1989). It is an effective agent against generalised convulsive and partial seizures, though it is of less value in myoclonic seizures (Eadie and Tyrer, 1989; Engel, 1989). Absence seizures do not respond to treatment with primidone. Due to adverse side effects including vertigo, dizziness, nausea, vomiting, ataxia and diplopia it is less well tolerated than other first line AEDs. It is, however, a useful adjunctive therapy particularly in patients who have shown a limited response to phenytoin or carbamazepine.

2.5.b.v **Ethosuximide**

Ethosuximide is one of the succinimide group of drugs, which were introduced specifically for the treatment of absence seizures (Engel, 1989). Ethosuximide was introduced in 1958 and is a highly effective agent against typical absence seizures (Shorvon, 1987). It may provide some protection against myoclonic seizures, but does not seem to be useful in other seizure types (Eadie and Tyrer, 1989). It is noted for its low toxicity. Dose related side effects include tiredness, headache and gastrointestinal disturbances (Browne, 1983; Eadie and Tyrer, 1989).

2.5.b.vi **Carbamazepine**

Carbamazepine is chemically related to the tricyclic antidepressants. It was first synthesised by Schinder in 1953 (Eadie and Tyrer, 1989), coming into clinical use as an anticonvulsant in 1962 (Shorvon, 1987). It is one of the most important antiepileptic agents and is the drug of first choice for tonic-clonic, clonic and partial (both simple and complex partial) seizures (Engel, 1989). It is reported to have fewer sedative effects than the other main-line antiepileptic drugs (PHT, PHB, PRM) and has been related to improvements in cognitive function when substituted for other AEDs (Trimble and Thompson, 1983). There is also a suggestion that this compound may have a psychotropic effect, though this topic remains controversial (Rodin, 1983).

2.5.b.vii **Sodium Valproate**

The valproate molecule was synthesised in 1881 (Eadie and Tyrer, 1989), but it was not until 1961 that its potential as an anticonvulsant agent was accidentally discovered (Eadie and Tyrer, 1989). It entered the armamentarium of anticonvulsant agents in the early 1970's. It is a simple branched-chain carboxylic acid with a broad spectrum of anticonvulsant action, being particularly indicated for the treatment of typical absence, myoclonic and generalised tonic-clonic seizures (Shorvon, 1987). Due to its broad range of action, it is a drug of choice for mixed seizure types (Engel, 1989). It is most effective against generalised convulsive and non-convulsive seizures, but it is may also be of some value in the treatment of partial seizures (Eadie and Tyrer, 1989). Sodium valproate has the reputation of being one of the least sedative of the antiepileptic drugs. This drug has a low side effect profile. Dose related gastrointestinal effects (anorexia, nausea, vomiting) occur in approximately 16% of patients (Engel, 1989); CNS side effects (sedation, ataxia, tremor) occur infrequently, in contrast to many of the other AEDs. Alopecia and appetite stimulation/weight gain may be problematic in some patients (Shorvon, 1987). Fatal hepatoxicity has been reported in a number of cases and is a risk which limits the use of this drug, particularly in children (Engel, 1989).

2.5.b.viii **Benzodiazepines**

The benzodiazepines were first synthesised by Dziewonski and Sternbach in 1933 (Dreifuss and Sato, 1982). In addition to their sedative-hypnotic and anxiolytic properties, a number of the benzodiazepines have anticonvulsant properties. Diazepam, nitrazepam and clonazepam are the main benzodiazepines used as primary therapy for epilepsy, although others may be useful as adjunctive therapy (eg. clobazam, midazolam) (Eadie and Tyrer, 1989). Sedation and the development of tolerance to the antiepileptic effect are the main restrictions on the use of these drugs.

Clonazepam (Rivotril/Clonopin): this 1,4-benzodiazepine was first evaluated in 1966 by Swinyard and Castellion, its use in routine clinical practice starting in the early 1970's. It is indicated for myoclonic seizures and non-epileptic myoclonic phenomena (Engel, 1989). Clonazepam is also highly effective against absence seizures, although ethosuximide remains the drug of choice for this seizure type due to the higher incidence of side effects and tolerance with clonazepam. Partial seizures, particularly those originating in the temporal lobes, may also respond to treatment with clonazepam (Eadie and Tyrer, 1989). Due to its broad spectrum of action, it may be useful in patients with mixed seizure types (Engel, 1989) . This drug is also used parenterally in status epilepticus. Side effects from oral administration are common with patients often experiencing ataxia, drowsiness and mood changes. Severe toxicity, however, is rare (Dreifuss and Sato, 1982). Hyperactivity in children has also been noted. Tolerance is a major problem, developing in 1/3 of patients within 3 month of starting therapy (Engel, 1989).

Nitrazepam (Mogodon): this drug is reasonably effective for myoclonic seizures, infantile spasms and the Lennox-Gastaut syndrome (Baruzzi et al;, 1982). The reflex epilepsies respond well to nitrazepam. Side effects are common, but mild and tolerance may be a problem.

Diazepam (Valium): while this drug is not an effective oral agent for the treatment of chronic epilepsy it has a major role to play in the treatment of status epilepticus. It is the drug of first choice for status epilepticus due to its rapid

penetration into the brain, its prompt therapeutic action and its rare toxicity (Schmidt, 1982). Oral use of diazepam as an anticonvulsant agent is rare due to the development of tolerance: it is useful, however, in treating accompanying psychiatric problems, for example, anxiety in the patient with epilepsy.

Clobazam (Frisium): this 1,5 benzodiazepine has a broad spectrum of antiepileptic properties, with a reduced incidence of sedative and motor side-effects (Engel, 1989).

Midazolam: this benzodiazepine may be useful as an intravenous anticonvulsant with a brief duration of action. It has been shown to abolish interictal spikes in the human EEG (Eadie and Tyrer, 1989).

2.5.b.ix **New antiepileptic agents**

A number of promising new agents have been introduced in recent years. Increasingly the development of new drugs for epilepsy is based on a logic rationale as to the mode of action of the drug in alleviating the epileptogenic process. Gamma-vinyl-GABA (vigabatrin), for example, was developed from theories on the role that levels of brain GABA play in the genesis of epileptogenic processes. Some of the drugs currently under investigation are listed here: lamotrigine, vigabatrin, oxcarbazepine, gabapentin, flunarizine and nimodipine.

## 2.5.c Surgical treatment of epilepsy

For some patients with epilepsy, surgery is a safe and effective alternative to treatment by pharmacological agents. Surgical treatment for epilepsy dates from 1886 and several surgical procedures are currently in use, including corpus callosectomy, hemispherectomy and stereotactic amygdalotomy (Hopkins, 1987). The most common treatment, however, is surgical resection of epileptogenic brain tissue particularly anterior temporal lobectomy. Surgical treatment is currently underused due to lack of surgical facilities and lack of information on indications for surgical intervention (Engel, 1989). Long term adverse sequelae of surgery are minimal due to improvements in surgical techniques and in fact there is

some evidence to suggest improvements in cognitive functioning after resection (Hopkins, 1987; Engel, 1989).

Several criteria are used to identify possible candidates for surgery. These are listed below (Hopkins, 1987; Engel, 1989):

1. Patient must have medically intractable epilepsy. This is generally defined as trials of all the major AEDs, alone and in combination, of at least 2 years duration.
2. Patient should have a definite diagnosis of a partial seizure disorder. A history of several seizure types may suggest multifocal and diffuse cerebral damage with a poor prognosis for resective surgery.
3. Patient should not have a low IQ or psychosis. Low IQ scores can be an indication of diffuse or bilateral cerebral damage which has a poor prognosis for surgery. Co-existing psychosis is also a contraindication for surgery. The benefits of surgery are limited in such cases as the patient may be as incapacitated after surgery as before due to the psychosis, even if the seizure disorder has resolved.
4. Patient should not have evidence of a progressive brain disorder or any medical contraindication to surgery.

Chronic epilepsy of long duration may result in the establishment of irreversible behavioural disturbances and psychosocial problems. For this reason, where applicable, early surgical treatment is advocated. The best results both in terms of seizure control and normal psychosocial adjustment are seen in patients with temporal lobe epilepsy who have been operated on between the ages of 12 and 30 years (Engel, 1989).

### 2.5.d Alternative approaches to the treatment of epilepsy

#### 2.5.d.i Diet

The ketogenic diet was introduced by Wilder in 1921 (Engel, 1989). Its antiepileptic effect is dependent on the degree of ketosis, which is in turn determined by the fat:carbohydrate ratio. Basically the diet requires the patient to ingest 1g of protein per kg of body weight, supplemented by fat (to ensure adequate calorie intake) with a minimal intake of carbohydrates. The major difficulty with this treatment is

non-compliance due to the unpalatable nature of the diet. In an attempt to overcome this problem the medium-chain triglyceride (MCT) diet was introduced in 1971. This diet is based on octanoic and decanoic acids and allows greater use of carbohydrate which increases its palatability, though compliance can still be a problem. This diet has been shown to be useful in all seizure types, but especially in medically refractory atonic, myoclonic and atypical absences in patients with Lennox-Gastaut syndrome (Engel, 1989). Other dietary manipulations have included supplements of amino acids and vitamins, although these have not been proven to be generally useful.

2.5.d.ii **Behavioural management**

This approach appears to be limited to the treatment of reflex epilepsies. Five types of behavioural treatments have been suggested (Forster, 1977).

1. Avoidance: simple avoidance of seizure-provoking stimuli.
2. Stimulus alteration: desensitisation through repeated exposure to similar stimulus.
3. Threshold alteration: complex reflex seizures are always followed by a refractory period in which presentation of the seizure-provoking stimulus will have no effect. Exposure to the effective stimulus during this period may result in desensitisation by increasing the seizure threshold.
4. Vigilance inhibition: voluntary diversion of attention. This is only effective if there is sufficient time between exposure to stimulus and onset of seizure.
5. Avoidance conditioning: can be useful in cases of self-induced seizures, using punishment as conditioning stimulus to prevent behaviour patterns that lead to seizures.

2.5.d.iii **EEG biofeedback training.**

This is based on the theory that operant conditioning aimed at increasing the occurrence of cerebral activity at a central rhythm of 12-15 c/sec (know as sensory motor rhythm SRM) will raise the seizure threshold and protect against seizures. The

difficulty is that while a significant decrease in seizures has been demonstrated using this technique, it has not been accompanied by enhancement of the 12-15 c/sec rhythm on the EEG. The method is also very time-consuming and expensive with few benefits and few controlled studies and is thus generally considered to be of limited use (Brown 1987; Engel, 1989).

2.5.d.iv **Psychological approach to treatment of epilepsy**

A number of psychological treatments have been used with some success (Brown, 1987). Reports in the literature are mainly anecdotal and controlled clinical trials are needed to fully assess the value of these treatments as adjunctive therapy. Nonetheless, they can be of use with individual patients and should not be disregarded. Approaches used have included: punishment and reward, relaxation techniques, hypnosis, psychodynamic psychotherapy and cognitive therapy.

## 2.6 QUALITY OF LIFE ISSUES IN EPILEPSY

The diagnosis of epilepsy can bring with it many problems over and above that of experiencing recurrent seizures. Stigmatization, social isolation, psychological problems, educational and employment difficulties have all been documented in people with epilepsy (Dodrill et al., 1984; Scambler and Hopkins, 1986; Thompson and Oxley, 1988; Levin et al., 1988). There are various medical (Duncan, 1990; social (Thompson and Oxley, 1988; Scambler, 1990) and psychological factors (Vining, 1987; McGuire and Trimble, 1990) which may influence the QOL of the person with epilepsy (see Table 2.9).

Where psychosocial difficulties exist in the patient with epilepsy these may be attributed to a number of causes. First, the disease process itself and any resultant brain damage or dysfunction may impact of the individuals' abilities. Secondly, treatment may play a role in producing impairments or disabilities which impact on the patients' QOL. Side effects of anticonvulsant medication, such as tiredness, double vision, cognitive deficits or the sequelae of surgery (for example, hemiplegia, memory disturbance or personality change), may affect the patients' QOL to as great or greater an extent than the occurrence of seizures. Thirdly, societal

Table 2.9 Contributory factors to impaired QOL in people with epilepsy

| Factor | Specific items |
|---|---|
| Medical | Seizure occurrence (frequency, severity)<br>Medication (intrusion/side effects)<br>Hospitalization (in-patient/out-patient) |
| Social | Stigmatization (felt/enacted)<br>Family dynamics (overprotection)<br>Employment difficulties<br>Legal restrictions (driving) |
| Psychological | Cognitive deficits (memory, concentration)<br>Intellectual decline<br>Psychiatric (depression, anxiety, behaviour disturbance |

attitudes may also play a major role in the determination of the QOL of a patient with epilepsy. Discrimination, stigmatization and non-acceptance of the individual with epilepsy are all too common (Bagley, 1972; Scambler and Hopkins, 1986). Collings (1990), in a study of factors related to general well-being in a group of patients with epilepsy, found that it was patients perceptions of themselves (their self-image) and their epilepsy that were most predictive of overall well-being.

Given the far-reaching consequences that the diagnosis of epilepsy may have on a patients QOL, it is interesting that few studies have attempted to objectively examine the impact of epilepsy on QOL. Whilst there has longstanding interest among researchers in the epilepsy realm in areas relevant to quality of life (for example, adequacy of cognitive, emotional and behavioural status, ability to work, social functioning, self-esteem etc), research work has tended to concentrate on assessing the incidence of psychosocial problems in patients with epilepsy (Harrison and Taylor, 1976; Rodin et al., 1977; Dodrill et al, 1984) rather than the impact of these difficulties on the individuals QOL. Hermann (1992) provides a review of QOL work in epilepsy and a useful summary can be also be found in Meador (1993).

Recent years have, however, seen an increased interest in formal studies of QOL (Hermann, 1993) as evidenced by increased attempts to develop epilepsy-specific measures (Vickrey et al, 1992; Baker, Smith et al., 1993, Perrine, 1993) and to examine determinants of QOL in this group of patients (Leonard, 1989; Chaplin et al., 1990; Collings, 1990a; Collings, 1990b; Collings, 1990c).

The measurement of QOL in patients with epilepsy is discussed in detail in Chapter 3 (Measurement of QOL). In relation to the areas of functioning considered important to (or predicitive of) QOL in patients with epilepsy, a number of recent studies have produced some interesting findings.

Leonard (1989) used a 50-item questionnaire to determine which items were considered most important to the QOL of patients living in a residential centre. Opinions were sought from relatives (n=25), staff (n=135) and residents (n=25). In

general, broad agreement across the three groups was seen, with the greatest importance being given to: 1) basic physical needs (warm, dry accommodation, adequate diet, clothing, availability of medical care); 2) seizure frequency; 3) independence (having personal possessions, opportunity for privacy, being ambulant; 4) social relationships/occupation (availability of close friends, facilities to encourage socialising) and 5) intellectual/creative needs. Some interesting differences, however, were apparent. Residents themselves placed greater importance on being in good spirits, being able to get out of the centre (for shopping/day trips etc), having close friends, having the opportunity for sexual relationships and having their own room than the other groups surveyed (relatives and staff).

Chaplin et al. (1990) interviewed paients about the impact and consequences of epilepsy and its treatment on their lives. They identified 21 areas of concern to people with epilepsy, covering medical, emotional, social and employment aspects (see Table 2.10).

As mentioned previously, Collings (1990a,b,c) found well-being in patients with epilepsy was most strongly associated with their own perceptions of themselves and their epilepsy. In addition, he noted that it was the discrepancy between an individuals perception of their current self (with epilepsy) and an anticipated self (without epilepsy) that was important in producing a greater sense of well-being. Other factors which were important to well-being were employment status, seizure control, diagnostic certainty and age.

In summary, the person with epilepsy may face psychosocial difficulties in a range of areas of life functioning. To date, however, little is known about the impact that these problems have on the quality of everday life of the individual with epilepsy. In addition, while such difficulties have been shown to exist, few attempts have been made to determine how important these areas of functioning are to the individual with epilepsy. One of the major obstacles to answering these questions has been the lack of a QOL measure suitable for use in patients with epilepsy.

Table 2.10 : Areas of concern identified by patients with epilepsy

| AREA | SPECIFIC CONCERN |
|---|---|
| Medical | Attitude towards accepting epileptic attacks |
| | Attitude towards label 'epilepsy' |
| | Fear of having seizures |
| | Problems with chronic medication |
| | Misconceptions about epilepsy |
| | Lethargy/lack of energy |
| | Sleep disturbance |
| | Distrust of the medical profession |
| Emotional | Lack of confidence in the future |
| | Change of outlook on life/self |
| | Depression or emotional reactions |
| Social | Concern about sexual relationships |
| | Concern about housing |
| | Lack of confidence surrounding travel |
| | Adverse reactions in social life |
| | Adverse reactions in leisure pursuits |
| | Difficulty in communicating with family |
| | Feelings of increased isolation |
| | Concern about platonic relationships |
| Employment | Fear of stigma in employment |
| | Concern about performance at work |

Source: Chaplin et al. (1990)

The following chapter reviews methodological considerations to be made when choosing or designing a QOL measure and examines some of the existing measures available.

# CHAPTER 3
# MEASURING QUALITY OF LIFE

## 3.1 INTRODUCTION

Recent years have seen increasing attempts to measure QOL issues as an outcome measure for clinical interventions. This has been paralleled by an increasing sophistication in our understanding of the QOL concept and measurement methods as evidenced by the reviews of Najman and Levine (1981) and Hollandsworth (1988). In their 1981 paper Najman and Levine reviewed studies published between 1975 and 1979 which claimed to assess the impact of medical interventions on QOL. They identified 23 studies and comment that the majority (20 out of 23) used only objective indicators of QOL, for example, hours worked, side effects and number of social relationships. This review was updated by Hollandsworth in 1988 who looked at papers published between 1979 and 1985. The main findings of interest were an increase in the number of published studies (69 in 1988 compared to 23 in 1981) and an increase in the number using subjective measures of QOL (60% in 1988 compared to 10% in 1981).

The measurement of quality of life is a complex, time-consuming and often evasive task. In the same way that there are a variety of interpretations and definitions of quality of life, there are numerous ways in which the assessment of quality of life can be approached. In the medical field, in particular, while there is a wide acceptance of the need to assess QOL in patients there is no 'gold standard' measure in existence for doing so. This gap between a recognised need to assess QOL and universally accepted measures (it is recognised that no one measure will be able to fulfil everyone's (or every study's) needs) has a number of consequences. At one end of the scale there are studies reporting the effects of illness/treatment on QOL who have investigated only a highly selected area of QOL for example, activities of daily living (ADL) or ability to participate in activities (Jayawardhana et al., 1989; Walker and Naylor, 1990). At the other end of the scale are the researchers who, having rejected existing measures, devise their own often with only a cursory thought given to assessing the psychometric properties of the measure (reliability, validity, sensitivity).

Whether choosing a test from QOL measures already in existence or developing a QOL tool for a particular application, there are a number of decisions to be made. For example, the choice (or development) of a method for assessing QOL may depend on the nature of the illness/treatment being studied and the purpose of the investigation (monitoring individuals over time, group comparisons of alternative forms of treatment or cost-effectiveness of various treatments). The following section outlines briefly the main issues relating to choosing or developing a QOL measure. This will then be followed by a brief overview of some existing measures of QOL.

## 3.2 CHOOSING A QOL MEASURE: METHODOLOGICAL CONSIDERATIONS

The initial purpose of reviewing the literature relating to the methodological aspects of choosing or designing a test of QOL was to help choose an existing measure which could be used or adapted for use in a population of patients with epilepsy. For ease of reading the issues will be discussed in terms of choosing a test. It should be borne in mind, however, that the same principles will generally apply when designing a QOL measure for a specific purpose or population.

The following section lists some of the questions which the researcher needs to consider when choosing a QOL measure.

### 3.2.a Why measure QOL?

QOL is currently a 'trendy' topic as evidenced by the burgeoning literature over the past 15 to 20 years. There is the suspicion, however, that many studies 'add on' a QOL measure because it is considered the politically correct thing to do, with little thought as to why they want to assess QOL (and often even less thought as to what the QOL concept means). This can be very frustrating for the researcher interested in QOL who chases an interesting sounding reference on QOL in their field of study only to find that the paper purporting to assess QOL in patients with epilepsy only reports, for example, ability to return to work following temporal lobectomy! If QOL research is to be widely accepted then workers in this field need to ensure that the scientific community as a whole understand not only 'what' the term refers to, but also 'why' it needs to be studied. QOL issues

are of particular relevance in chronic disease where treatment is prolonged and non-curative (Schipper, 1983). In addition, it can be argued that for certain situations there is an ethical obligation to assess and provide information on QOL issues (Levine, 1990). The reasons for studying QOL will vary according to the perspective of the researcher, whether clinically or industry based (Morris, 1990; Henderson-James and Spilker, 1990).

As in any area of study, QOL has both its supporters and detractors. Those who support QOL research view improved QOL as the ultimate reason for providing health care with an associated need to move way from the use of laboratory scores as outcome to an overview of the patient as an individual functioning within society as a whole. In contrast, detractors argue that were it not for laboratory-based research, many of the treatments and drugs in common use would not be available and in addition that QOL data are 'soft' and measurement methods vague (Schipper, 1983).

It is apparent from reading the literature that the main stumbling blocks in the acceptance/wide scale use of QOL measures are a) the feeling of clinicians that the measures are 'soft' and therefore unreliable and b) the time taken to assess QOL. From a philosophical point of view the majority of health workers recognise the merits of attempting to address QOL issues, but as mentioned above, the 'softness' and perceived unreliability of the data and the impracticality of many of the measurement methods deter them from the routine assessment of QOL. In defence of QOL measures, while it is certainly the case that no 'gold standard' exists, the criticism of 'softness' is, in many cases unfounded. There are a number of measures in existence (for example, the Sickness Impact Profile and the Nottingham Health Profile) which have undergone extensive psychometric testing and have demonstrable reliability, validity and sensitivity. In addition, there are a wide variety of situations in which information relating to QOL can be of value: to improve clinical decision making and patient care; to measure the efficacy of medical interventions; to assess quality of care; to decide on the necessity and appropriateness of treatments; to estimate

population needs for planning and resource allocation; to gain a better understanding of the causes and consequences of differences in health; to guide basis science, for example, the development of acceptable dosing regimes; (Ware et al., 1981; Sugarbaker et al., 1982; Schipper, 1983; Wiklund et al., 1986; Smart and Yates, 1987; Kaufman, 1989).

The study of QOL may have other benefits, for example, it has been suggested that asking about QOL issues can result in an improved doctor-patient relationship (Sugarbaker et al., 1982) and improved compliance with treatment (Testa, 1987; Wenger, 1988).

In summary, there are a variety of reasons for studying QOL and these need to be carefully considered when planning a QOL study. Many facets of the study design, for example, choice of measurement method, timing of assessments and population studied will depend upon the 'raison d'aitre' for the study. As an illustration, a study which is interested in using QOL to assess an individual over time and to plan treatment may choose a measurement tool which provides a profile of scores within identified areas of functioning; in contrast, a study which aims to make group comparisons based on alternative treatments may choose a QOL measure which provides one measure (a global QOL score).

3.2.b **What do I want to measure?**

Any study of QOL should start with a clear understanding of the QOL concept and a working definition which outlines the type and minimum amount of data which need to be collected. Chapter 1 discusses the definition of QOL in detail, but as a guide, generic QOL assessments should cover at least physical, mental and social aspects of life functioning (Spitzer, 1987).

In addition, there may be disease-specific symptoms which are likely to impact on a patients QOL and need to be measured.

The nature of the study will also influence decisions relating to what should be measured. For example, if a study is evaluating the outcome of a specific intervention then it is advisable to use measures that assess expected effects of that intervention. It is of little or no value (and a waste of resources) to measure something that the intervention cannot

possibly change or which is unlikely to change within the time frame of the study (Ware et al., 1981).

The nature and degree of an illness or disease may influence the extent of the QOL assessment. For example in a severe disease with many functional limitations, the capacity to perform activities of daily living (ADL) may be of greater significance than in a less disabling condition where other areas (for example social interaction, family relationships, work ability) may be of more importance (Alexander and Willems, 1981; Wiklund et al., 1986). In the former an argument could be made for limiting the areas of life functioning included in the QOL assessment, while the latter case would require a more extensive assessment (in terms of areas of life functioning included). This is an interesting suggestion and is in line with Maslow's hierarchy of needs which states that higher order needs (self-esteem, self-fulfilment) only become important once lower needs (physical comfort, warmth) have been met (Maslow, 1970). It therefore follows that for someone who is physically limited this may be the most important determinant of their QOL and needs to be measured in detail. This highlights the individual nature of QOL and also the fact that no single QOL measure will be suitable for all diseases and situations. When deciding on the relevant content of a QOL assessment for a particular situation it is important to consider whether the measure will be used to explore one, specific disease (for example, breast cancer) or a family of diseases (for example, cardiovascular disease) (Schipper, 1983).

Decisions also need to be made about whether the QOL measure addresses issues surrounding the role that the expectations and aspirations held by an individual play and the relative importance of the areas investigated (Briscoe, 1985, Liang and Robb-Nicholson, 1987). For example, does it ask the patient to compare their current situation with some 'ideal' or does it ask them to rate the importance they place on the areas of functioning assessed?. It is likely that the relative importance attached to each QOL domain will vary from individual to individual, as will the willingness to accept

increased discomfort for a potential increase in survival (Fayers and Jones, 1983).

While it is important to define what aspects of QOL are considered important and should be included in the assessment tool, it is recognised that no measure can cover all possible consequences of an illness or treatment (Liang and Robb-Nicholson, 1987) as these will not always be known to the researcher. This is particularly relevant to chronic disease needing long term therapy in which unexpected long term side-effect may impact negatively on a patients QOL. Researchers need to be aware when interpreting QOL data that even the lengthiest, most comprehensive assessment may exclude areas of importance to an individual.

When deciding on what aspects of QOL to include in a study it is important that a consensus is achieved among all those who are concerned with the patient (doctors, nurses, relatives, patient) and the researchers as to the definition of QOL and the core variables which need to be included (Schipper, 1983; Greer, 1987). This has implications for compliance and is particularly important if a QOL measure is to be used routinely in a clinical setting.

3.2.c **How do I measure it?**

Decisions also need to be made about how QOL is to be measured, for example, whether by objective or subjective indices; whether a single index is required or a profile; whether the assessment is to be made by a professional or the individual themselves; whether a battery of tests are to be used or a generic QOL measure. These decisions will be influenced by a number of factors including the nature and purpose of the study, the type of population being studied, the time available, the number of other variables being assessed as part of the study, the personnel available and the personal preference of the main researcher. Some guidelines about developing new measures are given by Jaeschke and Guyatt (1990). The issues surrounding these types of questions are summarised below:

3.2.c.i **Objective versus Subjective Measures**

Early QOL work, particularly that arising out of the social indicators movement placed a heavy emphasis on measuring

observable or 'objective' aspects of QOL, for example, housing and level of income. The shortfalls, however, of the reliance solely on objective indicators as a measure of individual QOL soon became evident and attempts to devise subjective indices of QOL were made (Campbell et al., 1976; Andrews and Withey, 1976). One of the main problems with the use of objective indicators is the poor correlation between objective indices and subjective experiences of QOL (Najman and Levine, 1981).

Although philosophically it is the individuals subjective evaluation of their QOL experience that is paramount, objective measures have traditionally been considered more reliable. This, however, is no longer the case as subjective measures can be demonstrated to satisfy reliability standards (Ware et al., 1981). Despite documented criticism of the use of objective indicators in studying QOL, such measures have been widely used, particularly in the early studies of QOL. Najman and Levine (1981) for example found a heavy reliance on objective measures (20 of the 23 studies reviewed used objective indicators alone). Recent years, however, have seen a greater use of subjective indices (Hollandsworth, 1988) with lesser reliance on objective measures as proxies for QOL.

Also related to this issue is the question of who does the QOL assessment - a professional (doctor, nurse), a relative/carer or the patient. It is sometimes felt that a judgment made by a professional is more 'objective' or gives a truer picture than a judgement made by the patient themselves. Mor and Guadagnoli (1988) point out that people often confuse who is doing the rating with 'objectivity' stating that 'objectivity' is not bestowed on a measure simply because a third person makes the observation.

In summary, the current trend in QOL research is towards measuring the 'subjective' experience of QOL. While this is welcomed, this does not imply that objective measures are meaningless. In some circumstances objective data (health, socioeconomic, employment etc) are needed to complement and help to understand the individuals subjective experience of QOL.

### 3.2.c.ii **Index Score or Profile of Scores**

This relates to whether or not a measure is required which provides a single score (or QOL index) or a profile of scores relating to functioning in a number of specified life areas (for example physical, social and emotional functioning). Some measures provide both (the SIP for example gives an overall score as well as individual scores for 12 life domains).

The decision as to which approach is most appropriate will depend upon a number of factors including the purpose of the study and the statistical analyses planned. The tradeoff seems to be between the simplicity of a single indicator and the loss of information that results from the aggregation of very different variables and the erroneous inferences to which this might lead (Ware et al. 1981).

### 3.2.c.iii **Proxy or Individual Assessment**

The issue of who makes the assessment of an individuals QOL needs to be carefully considered. Should it be made by a health professional, a relative or carer or the individual themselves?

Wiklund et al. (1986) state 'the patient's subjective perception is a sensitive measure of the effectiveness of (medical) intervention provided that it is evaluated scientifically'. Similarly, Barofsky (1984) comments that 'when properly executed, a quality of life assessment is a clear and unequivocal political statement - a statement reflecting the wishes and needs of those who receive medical care'. If the philosophical argument is accepted that the only rationale/justification for providing medical treatment is to improve or at the very minimum maintain, QOL and it is also acknowledged that QOL is an individual and subjective phenomenon (see chapter 2 for full discussion of properties of QOL) then the inference would be that person best placed to provide data relating to their QOL is the individual themselves.

There are, however, circumstances in which it is not practical or possible to ask the patient themselves about their subjective experiences of QOL. Examples include those who are critically or terminally ill, the very young, the confused elderly and those with a severe mental handicap. In

such instances it is better to ask a third party to estimate an individuals QOL rather than make no assessment at all. This may be either a health care professional (doctor, nurse, other) or a relative, carer or friend. Fallowfield (1990) comments that clinicians often prefer rating scales that they can complete on the basis that they use clinical judgement and can be more objective than patients, but as mentioned previously, an 'external judgement' does not necessarily infer 'objectivity' (Mor and Guadagnoli, 1988). In addition, studies have demonstrated poor correlations between doctor and patient ratings and between different doctors and other health professionals (Fallowfield, 1990).

One situation in which the use of a proxy to evaluate an individuals QOL is when the impact of an individuals illness on family life is sought. This is a neglected area of research. Discrepancies in subjective assessments of QOL made by the patient and by a relative/carer can provide interesting insights into the impact of illness/treatment not only on the individual, but also on their family and its structure (Wellisch, 1984).

### 3.2.c.iv **Battery versus Generic Measures**

There are a number of advantages and disadvantages to using a battery approach to the assessment of QOL. On the plus side, it enables a comprehensive assessment to be made covering many aspects of an individuals life; it can be tailored to fit a particular study and it allows the use of existing and, hopefully, well validated questionnaires. On the minus side, it can make the assessment lengthy; individual instruments will possess differing psychometric properties which makes interpretation of change difficult and; it is difficult to summate the scores from a range of tests into an overall QOL score. For example, if a patient scores well on measures of physical functioning and poorly on social aspects, what is their overall QOL? This is likely to depend on the importance the individual attaches to each of these abilities and is something which is generally overlooked in QOL assessments.

In contrast, generic measures will cover a range of areas of life functioning which can be used to provide a profile

score or can be summed into a total QOL score. In addition such a measure will have been developed from one perspective unlike a battery of measures which are likely to have been developed for a variety of populations and purposes.

Sugarbaker et al. (1982) provides an example of the use of the battery approach to assessing QOL to compare treatments in patients with soft tissue sarcoma. They felt that the impact of cancer on the patients' physical, psychological and social functioning would be important determinants of the patients QOL after treatment and chose a number of measures to assess these facets of the individuals life. The measures they used included the SIP, Katz's Activities of Daily Living Scale (patient assessed), the Bartel Function Scale (assessment of functional capacity by health care professional), the PAIS and an economic assessment (51 item questionnaire assessing change in earning potential, home functioning and cost of treatment).

In contrast, an example of a generic approach to assessing QOL is the Sickness Impact Profile (Bergner et al, 1981) which covers 12 areas of life functioning (domains) incorporating aspects of physical function, psychological status, social behaviour and daytime/recreational activities situation. In addition, scores from these can be summated to provide overall assessments of physical, psychosocial and overall functioning.

### 3.2.c.v **Study design**

One factor that is often overlooked in assessing QOL is the study design. This has implications both for the choice of measure and for the credence given to the subsequent study findings.

Issues to consider include when and how often QOL assessments should be made. The choice of time scale used in the study will depend upon the natural history of the illness and the timing and pattern of treatment. For example, in a study of the effects of a medical intervention on QOL if the interval is too short then it is unlikely that any significant change in QOL will have occurred; if the interval is too long then QOL may have changed dramatically for reasons unrelated to the medical intervention.

Ideally, a QOL assessment should be performed before during and after an intervention to provide a continuous picture of any changes (Fayers and Jones, 1983). The retrospective collection of QOL data (eg. 'how satisfied were you with your QOL before this treatment?') has a number of difficulties, including inconsistencies of memory and the patient's desire to please the doctor and answer 'correctly'.

Patient cooperation will also be influenced by the timing and number of repeated assessments, particularly if the QOL instrument is lengthy and time consuming to complete. Many repeat assessments may discourage patients from continuing in a longitudinal study and/or affect the quality of the data collected (for example producing a high rate of missing responses).

Another important issue particularly in the design of comparative studies is the choice of control group. Having an illness is likely to alter an individuals value systems and if a 'healthy' control is used to validate a measure this may result in discordant findings (Barofsky, 1984).

### 3.2.c.vi **Questionnaire Format**

A patients' response to a questionnaire will depend upon a number of factors including the perceived relevance of the questions and the length and social acceptability of the items. Careful consideration of the questionnaire format is important to ensure patient cooperation and accurate, valid and reliable data. Barofsky (1984) suggests that how a person is asked to make a judgement about their QOL is a major methodological issue in QOL assessment. A patients' judgement will be influenced by whether they are asked to make retrospective assessments or to compare their current situation with an 'ideal' state. Similarly, Fayers and Jones (1983) point out that the way in which questions are worded (whether negatively or positively) will influence a patients response. Ideally, questions should be relevant, easy to understand, phrased in a way which allows negative and positive responses and use a short time scale (for example, asking about situation in past 24 hours rather than asking patient to make assessment about situation over past 3 weeks).

### 3.2.d How practical is the measure?

Having decided why, what and how you want to measure QOL, the next step is to examine the practicality of the measure available in terms of administration and analysis. Ultimately the choice of a measure will depend to a large extent on its practicality. Wiklund et al. (1986) state that 'a QOL scale for repeated clinical use must be short, simple, easy to understand, to administer, to record and to score'.

Practical issues to be considered include the suitability of the questionnaire for the population to be studied; the type of administration needed (whether the questionnaire is administered via an interviewer, by telephone interview or self-administered), the length of the questionnaire; type of scoring method (time to do, complexity) and the ease with which the scores can be interpreted (for example, the availability of published norms).

#### 3.2.d.i **Suitability**

This is probably one of the most important questions to consider when choosing a QOL measure for a particular study - 'Is it suitable for the population to be studied?' Does it ask questions which are relevant to that population? The relevance of items has two facets: first, that items considered vital to the study are not excluded (for example, areas which are known or expected to be affected by treatment like sexual functioning or emotions) and second that all items included are germane/pertinent to all the target population. For example, a questionnaire with a heavy bias towards questions relating to functioning at work may not be relevant in a study in which the target population is predominantly housewives.

#### 3.2.d.ii **Ease of completion**

Relevant factors which relate to the ease with which the QOL measure is completed include the length of the questionnaire, the ease with which questions are understood, the mode of administration (this has implication both in terms of time and cost) and the response format.

The length of the questionnaire is of particular relevance for self-administered measures with implications for respondent cooperation, missing responses and accuracy of data.

The ease with which the questions are read and understood is an important issue and it is recommended that wherever possible questionnaires should use the native language of the subjects (Wiklund et al., 1986). Fallowfield (1990) points out that many existing measures have been developed in America and that many English-speaking people find American English confusing. Other important factors to consider here include the layout of the questionnaire; the availability of large print versions if the questionnaire is to be used in an ageing or visually impaired population and the avoidance of socially-loaded questions (Fallowfield, 1990). If a questionnaire contains many socially loaded questions then the responses may not be a true reflection of the QOL of the patient.

Another important consideration relating to the ease of completion is the time-frame of the questionnaire. Questions are often phrased to relate to a certain period of time, for example, 'how much pain have you had in the last week' or 'what has your mood been like in the past month'. The longer the time period the more likely it is that the responses will be unreliable, due to inaccuracies of recall (Fallowfield, 1990).

The mode of administration will depend to a large extent upon whether or not financial resources are available to provide trained interviewers. It is generally acknowledged that more accurate data with fewer missing responses are collected by trained interviewers, yet cost implications often mean that self-administered versions of questionnaires are preferred. The mode of administration can also influence the psychometric properties of the measure (see Bergner et al., 1981 for an example of how differing modes of administration produce different results in terms of reliability, validity and sensitivity).

3.2.d.iii **Response format**

The choice of response format has implications for the ease with which the questionnaire is completed, the time is takes to complete and the ease with which it is scored. It needs to be easy to understand, unambiguous and allow the assessment of both positive and negative effects on QOL (Jern, 1985). The choice of response format lies between open or closed questions (Fayers and Jones, 1983). Open questions are unrestrictive, but less easy to categorise and analyse than closed questions. When closed questions are used it is necessary to decide whether or not to use linear analogue (continuous) or categorical scales. The advantages of linear analogue scales include their simplicity, sensitivity, reproducibility and they allow greater discrimination (Clark and Fallowfield, 1986). The theory that a continuous scale allows greater discrimination, however, has not been supported by empirical studies which have found little difference in reliability and validity between continuous and categorical scales (Remington et al., 1979). Disadvantages of linear analogue scales include the time taken to score; some patients find the concept difficult to understand; there is often a questionable relationship between the score and the subjective experience; the existence of floor and ceiling effects (although this is common to all scales with fixed end points); the score does not include weighting and the clinical significance of LASA ratings is not always clear (Clark and Fallowfield, 1986; Fallowfield, 1990). Categorical scales are easier to administer, score and analyse although they too have a number of difficulties. First, ensuring the appropriateness of the categories; second, the reliability of the scale is dependent upon the number of categories used (four or five is generally considered acceptable; third, a decision has to be made whether or not to allow a middle choice (3 point scale or 4 point scale); fourth, labelling can lead to inconsistencies between subjects (for example, one person's interpretation of severe pain may differ widely from another based on past experience, individual pain thresholds etc).

3.2.d.iv **Ease of scoring**

A questionnaire which is easy to complete, but difficult and complex to score is unlikely to be used routinely. Factors which can make scoring complex include weighting of individual items before summation or summing non-adjacent items to calculate a category score.

3.2.d.v **Ease of analysis and interpretation**

How an individuals score on a QOL measure is interpreted will depend on the purpose and design of the study. The availability of published norms enables comparison of an individual score with group norms (derived from people of similar age, sex, social class, educational background or disease state) (Fallowfield, 1990).

In summary, although studies differ in purpose and design, the ideal instrument should be comprehensive, quick to complete and score and simple to interpret.

3.2.e **What are the psychometric properties of the measure?**

In order for the information collected by a QOL measure to be useful, the measure needs to be shown to be reliable, valid and sensitive. These properties can vary across populations and settings and thus need to be redefined for any new situation in which the QOL measure is being used. Re-evaluation is thus needed if the measure is being used in a different patient population from that in which it was developed, if it has been translated into another language or is being used in a different cultural setting (Hunt et al., 1986). Turner (1990) suggests that the acceptability of a measure's psychometric properties is dependent upon the use for which the measure is intended (for example, whether it is used to discriminate between different clinical groups or to detect changes over time within individuals). He quotes the work of Kirschner and Guyatt (1985) who propose that assessment scales can be divided into three categories: discriminative, predictive and evaluative (see Table 3.1). Discriminative scales separate patients/subjects into groups based on diagnostic criteria; predictive scales categorise patients on the basis of a known criteria or 'gold standard'

Table 3.1: Major Issues in Scale Development (from Kirshner and Guyatt (1985) reproduced in Turner (1990)

| | DISCRIMINATIVE | PREDICTIVE | EVALUATIVE |
|---|---|---|---|
| Item Selection | Tap important components of the domain; univeral applicability to respondents; stability over time | Statistical association with criterion measure | Tap areas related to change in health status; responsiveness to clinically significant change |
| Item Scaling | Short response sets which facilitate uniform interpretation | Response sets which maximise correlation with the criterion measure | Response sets with sufficient gradations to register change |
| Item Reduction | Internal scaling or consistency; comprehensiveness and reduction of random error vs response burden | Power to predict vs respondent burden | Responsiveness vs respondent burden |
| Reliability | Large and stable intersubject variation; correlation between replicate measures | Stable inter and intrasubject variation; chance corrected agreement between replicate measures | Stable intrasubject variation; insignificant variation between replicate measures |
| Validity | Cross-sectional construct validity; relationship between index and external measures at a single point in time | Criterion validity; agreement with criterion measure | Longitudinal construct validity; relationship between changes in index and external measures over time |
| Responsiveness | Not relevant | Not relevant | Power of the test to detect a clinically important difference |

and evaluative scales are used to detect clinically important changes in ability. Turner (1990) points out that misleading results can be obtained if a scale developed for one purpose is used in a different situation (for example using a discriminative scale for evaluative purposes).

These issues are discussed in greater detail in textbooks on psychological testing/psychometric theory (for example, Cronbach, 1960; Anastasi, 1976; Nunally, 1978) and a simple introduction can be found in Fallowfield (1990). The following section will cover briefly the main issues relating to each of these properties.

### 3.2.e.i **Reliability**

The reliability of a measure relates to the amount of error or 'random noise' contained in a score. All scores will contain a certain amount of 'noise' or random error and while it is not possible to eliminate error completely, the degree to which it is minimised reflects the extent to which the score can be considered stable and reproducible (Nunally, 1978). The reliability coefficient indicates the proportion of reliable information conveyed, as opposed to random error, that a score contains. For example, a coefficient of 0.70 would indicate that the score consisted of 30 per cent noise (Ware et al., 1981).

When choosing a measure it is necessary to determine an acceptable level of reliability and this decision may depend on the type of measure being used, the population being studied and the purpose of the study. Poorer reliabilities are generally expected from short scales (single-item scales rather than multi-item scales) and from disadvantaged populations (less education, lower income) (Ware et al., 1981). Generally, reliability coefficients of 0.7 or greater are acceptable as evidence of reliability (Selby et al., 1984), however, the degree of reliability needed will vary according to the purpose of the study. Higher reliabilities are needed for studies making comparisons over time in individual cases than for studies making group comparisons, for example, Ware et al. (1981) suggest that a reliability coefficient of 0.90 would be necessary for the former whereas

in the latter case a coefficient of 0.50 would be sufficient. The cost of achieving a high reliability coefficient is high in terms of time and resources (more items and more observers are needed) and thus it is important to determine at an early stage in a study what degree of reliability will be considered acceptable.

There are three main types of reliability that are usually determined: test-retest reliability, internal reliability and inter-observer reliability.

Test-Retest Reliability

This relates to the extent to which the scores on a measure are repeatable and consistent and is of particular importance in studies involving repeated assessment of QOL. It is usually assessed by asking a sample population to complete the same test on two occasions. Comparisons of the scores on both occasions can be made by plotting a scattergram of the test-retest scores (Priestman and Baum, 1976) or more usually by calculating a correlation coefficient. The time interval between the two completions is important: too short a time interval and the subjects may remember their previous responses resulting in an erroneously high correlation coefficient; too long an interval and external variables may have affected an actual change in QOL which would result in a low (but understandably so) coefficient. Despite their wide usage, the applicability of the correlation coefficient as a means of assessing test-retest reliability has been questioned (Fayers and Jones, 1983). Altman and Bland (1983), for example, suggest a number of alternatives to the use of the correlation coefficient including plotting the within-patient standard deviation against the mean.

Internal Reliability

This measures the extent to which different items within a particular scale are measuring the same characteristic and is of particular importance in evaluating whether or not items being grouped together actually measure the same underlying trait. A common method used for assessing internal reliability is the split-half technique in which an instrument is divided into two equal parts and the correlations between the scores

on each part are calculated (McEwen, 1988). An alternative approach is to estimate the correlations between all possible pairs of items (McDowell and Newell, 1987). Cronbach's alpha coefficient and Kuder-Richardson 20 are two widely used statistics to assess internal reliability (McDowell and Newell, 1987). While there is no fixed correlation which conclusively establishes reliability, internal reliability coefficients of 0.85 or greater are generally considered acceptable (McDowell and Newell, 1987).

Alternate Forms Reliability

This only applies to situations where two or more instruments have been developed in parallel which measure the same attribute(s). This is assessed by administering the two (or more) instruments on the same occasion and examining the correlation between their scores (McEwen, 1988).

Inter-Observer Reliability

This relates to the extent to which the scores on a test are affected by who administers the test. This is particularly important for a QOL measure which is to be used for a large-scale, multi-centre trial in which a number of researchers/interviewers will be administering the questionnaire. Methods used for calculating intra-observer reliability include Kendall's index of concordance (W) (Patrick and Erickson, 1988), Cohen's test for agreement between two or more judges and weighted Kappa (Fayers and Jones, 1983)

### 3.2.e.ii **Validity**

Validity refers to whether or not an instrument measures what it is intended to measure. There are three basic types of validity: content, criterion and construct (Kaplan, Bush and Berry, 1976). All other forms of validity (for example, predictive, convergent, divergent, factorial) can be subsumed into these three categories.

Face and Content Validity

Face validity refers to the apparent validity of individual items based on their wording, while content validity refers to how well the measurement instrument covers all aspects of the concept being assessed (for example, QOL). Face and content validity represent nonempirical approaches to the assessment of validity and, taken in isolation, do not provide a sufficient basis for choosing one test over another, however, Ware et al. (1981) suggest that an examination of face and content validity is a useful starting point when choosing a measure. Doing so ensures that the measure does address all the areas necessary (and avoids the confusion generated where different researchers label similar attributes different), it is easy to do and often the only option when limited additional information regarding empirical testing of validity is available. One of the difficulties with establishing content validity in particular is that the acceptability of the content of a measure may be dependent on the 'expert' or group of 'experts' who are doing the assessment (Turner, 1990). Although content validity is generally assessed non-empirically, factor analysis techniques have been used to establish, empirically, which items are assessing similar underlying traits (or factors). For factor analysis to be meaningful a number of criteria need to be fulfilled: 1) the variables analysed should be measured on an interval scale level; 2) the response distributions should be normal and 3) there should be at least five times more respondents in the sample that there are variables to be analysed (Comrey, 1978).

Having established face and content validity, there are a number of statistical procedures which can be employed to empirically evaluate the validity of an instrument and these are discussed below:

Criterion Validity

Criterion validity relates to the extent to which an observed measure corresponds to some observable criterion variable which measures accurately the phenomena of interest (Andrews and Withey, 1976). Criterion validity is the simplest way of establishing validity, but is only applicable where an

accepted criterion or 'gold standard' exists against which to test the new instrument (for example, where the new instrument is a simpler, shorter version of a standard instrument). There are two subcategories of criterion validity: concurrent and predictive validity. Concurrent validity is assessed by calculating the correlation between the 'new' instrument and the 'criterion' instrument in the same population. Predictive validity is used when the an instrument is intended to be used to predict future health status/performance/QOL. It is tested prospectively by comparing the scores on the instrument obtained at the start of the study with the patient outcome at the end of the study. If the 'new' measure successfully predicts a future criterion value (for example, the current score predicts future health status) then this is evidence of predictive validity.

Construct validity

Construct validity refers to the relationship of an observed measure to a theoretical construct (or concept) (Andrews and Withey, 1976). It applies to the process of establishing validity through several validation mechanisms and is commonly used to assess the validity of new instruments for which no 'gold standard' exists. This method generally involves formulating and testing a series of hypotheses, normally based on the degree of correlation between the 'new' instrument and measures of similar or different traits; the degree to which the instrument performs in line with these will determine the degree of confidence in the instruments' validity. Thus, as Mor and Guadagnoli (1988) state 'the more ways in which the behaviour (of an instrument) is congruent with expectations, the more confident we are that is measures what we thought it did'. The multi-trait, multimethod approach suggested by Campbell and Fiske (1959) provides a framework for the assessment of construct validity and is considered a powerful validation strategy (Mor and Guadagnoli, 1988). This approach tests the performance of an instrument against the following hypotheses: 1) that the scores on the instrument will correlate with measures assessing similar traits (convergent validity) and 2) will not correlate to a significant degree

with measures of dissimilar, unrelated traits (divergent or discriminant validity).

General issues relating to validity

Given that there is no definitive way of proving validity, McDowell and Newell (1987) raise a number of issues which are important when interpreting validity information:

1 Where no 'gold standard' exists it is likely that the correlation between the 'new' and existing measures will not be high, yet few studies declare what level of correlation are acceptable to demonstrate validity. Often authors report findings and state that a measure is thus valid! A reasoned argument needs to be made (preferably before the empirical testing is done) as to what degree of correlation between the 'new' and existing measures is acceptable evidence of validity.

2 When deciding on what degree of correlation is acceptable it needs to be remembered that, due to measurement error, the maximum correlation that can be obtained is the product of the square roots of the reliabilities of both measures. If reliability coefficients for both measures are known it is possible to compare the observed correlation to the maximum theoretically possible.

3 Validity coefficients may be interpreted in the light of values typically seen. For example, in their book, McDowell and Newell (1987) review many rating scales and questionnaires and report concurrent validity coefficients ranging from 0.2 to 0.6.

When considering the validity of a measure it is also important to remember:

1. The extent to which external variables (mood, life events) may influence scores (Ware et al., 1981)
2. No test is inherently valid; rather a test is valid with regard to a specific purpose, range and sample (Shumaker et al., 1990). Thus a measure validated in one population or situation may not be valid in a different setting (Ware et al., 1981).

3. Evidence of validity for a measure does not automatically imply that the measure will be the most appropriate for a given study. Careful consideration needs to be given to the content and other practical issues. For example, it may not measure aspects considered important to the study or it may contain questions which have no relevance to the study population (Ware et al., 1981)

4. It needs to be remembered that the use of selected items from an instrument is possible. It is often suggested that a measure is invalidated if items are omitted. Information and time is wasted if a study has specific aims and excess data is collected. However, it is often useful to use the whole instrument if the effects of an illness/treatment are uncertain (Ware et al., 1981).

In summary, establishing the validity of a measure is a difficult, if not impossible task. Flanagan (1982) suggests that the only valid unit of study is the individual and that results will be meaningless unless interpreted in relation to the individual. Roberts (1990) states that 'complex methodologies yield huge amounts of data, but the basic problem of validity has yet to be resolved. Therefore a crude estimate of an important variable is preferable to a precise, but irrelevant measure'.

3.2.e.iii **Sensitivity**

Turner (1990) differentiates between sensitivity and responsiveness. Sensitivity is viewed as the extent to which a measure is able to demonstrate differences due to disease (for example, the ability to discriminate between 'ill' and 'healthy' populations). In contrast, responsiveness is defined as the ability of a measure to detect clinically important changes when they occur. It is possible for a measure to be sensitive, but not responsive. For example, a single assessment comparing different patient populations may demonstrate the sensitivity of a measure to detect varying degrees of illness, however, the same measure may not be responsive to detecting small (but clinically significant)

changes within a particular population.

As with validation, there is no direct method for assessing sensitivity. Sensitivity/responsiveness is usually inferred by the extent to which the measure behaves as expected. For example, an instrument may be administered to two populations and it may be hypothesised that population A will demonstrate significant impairment when compared to population B. If this hypothesis is borne out by the scores then this provides some evidence of the sensitivity of the measure. Responsiveness would be assessed in a similar way, but using a longitudinal design in a single population and the presence of some external circumstance which may or may not be expected to influence scores on the instrument (for example a medical intervention or major life event).

A careful balance needs to be maintained between responsiveness and test-retest reliability. A highly responsive measure which is influenced by minor and transitory changes (for example, mood) would be considered unreliable, while a highly reliable measure may be insensitive to small, but clinically relevant changes.

## 3.3 REVIEW OF EXISTING MEASURES AND THEIR APPLICABILITY TO THE INDIVIDUAL WITH EPILEPSY

There are a myriad of measures which have been developed to assess QOL varying in comprehensiveness, target illness and degree of validation. It is beyond the scope of this thesis to examine each of these in detail; this information can be found in a series of books and review articles (Clark and Fallowfield, 1986; McDowell and Newell, 1987; Fletcher et al., 1987; Walker and Rosser, 1988; Teeling-Smith, 1988; Kaplan, 1988; van Knippenberg and de Haes, 1988; Goodinson and Singleton, 1989). The purpose of this review is to consider those measures which could be of possible use in evaluating the QOL of a population of patients with epilepsy., The choice of measures to be included in this review was based on a set of criteria derived from a working definition of QOL and a careful consideration of some of the methodological issues involved when attempting to measure QOL. The working definition of QOL and how it was derived is detailed in

Chapter 1, but to recap briefly, QOL is considered to consist of five fundamental characteristics:

1. Multidimensionality: QOL covers, at a minimum, physical, cognitive, emotional, social and economic/employment aspects of life.
2. Individuality: only the person themselves can provide a true judgement on their QOL.
3. Role for expectations: the gap between a persons achievements and their aspirations (or expectations) play an important role when evaluating their QOL.
4. Relationality: QOL is seen as a relational phenomenon where judgements about current QOL are based on comparison with external criteria (past abilities, peers, significant others).
5. Changeability: QOL is a not a static phenomenon, with changes relating to alterations in objective circumstances (eg physical health) and subjective perceptions (eg. expectations).

From a methodological viewpoint, it was felt that there was no advantage in being too prescriptive at this early stage in attempting to identify a measure suitable for use in people with epilepsy. It was considered, however, that for the purposes of this study, a generic QOL measure would be most appropriate (as opposed to taking a battery of measures approach). The following criteria were considered necessary for a QOL measure which conformed to our ideological formulation of the QOL concept and which would be applicable to people with epilepsy. At a minimum (for inclusion in this review) measures should fulfil criteria 1-4.

1 The measure should be generic.

2 It should be comprehensive covering a broad range of life aspects. Ideally it should include physical functioning, cognitive status, emotional state, social functioning, economic/employment situation.

3 It should have published data available relating to reliability, validity and sensitivity.

4 It should allow a subjective assessment by the individual themselves. Scales involving assessment by professionals or other third parties were not considered in this review.

5 It should be well-known and used (though it is recognised that this is not necessarily an indication of a good, valid test).

6 All items in the questionnaire should be relevant to the person with epilepsy.

7 The questionnaire should include items assessing specific functions recognised as common problems in epilepsy eg memory, social functioning, unemployment and stigma.

8 The questionnaire should not rely heavily on assessment of physical status. The majority of patients with epilepsy are physically fit apart from intermittent seizures and it is now well recognised that many of the difficulties faced by the person with epilepsy are non-physical.

9 Ideally, the measure should attempt to assess the individuals expectations. For example asking questions about 'how they would like to be' or 'the ideal life'.

10 Ideally, the measure should ask the patient to make comparisons of their current situation with other situations/people, for example, with their situation before illness.

### 3.3.a Karnofsky Performance Index (Karnofsky and Burchenal, 1949)

This scale was never seriously considered a suitable measure for assessing the QOL of people with epilepsy due to its heavy bias towards assessing physical function. It is, however, one of the most widely used scales in studies purporting to measure QOL (particularly the early QOL studies) and thus warrants at least a brief mention in this review. It is still a useful and valid measure of health status (Grieco and Long, 1984), but provides little information about QOL as the concept is currently defined (as a subjective, multidimensional phenomena) (Clark and Fallowfield, 1986).

This is a physician-rated scale where a persons'

functional abilities are rated on a descriptive, percentage scale ranging from 100% (normal, no complaints) to 0% (dead). Its advantages are its speed and simplicity and it is liked by clinicians (as they do the ratings!). Full details of the descriptive categories are given in Table 3.2. Its drawbacks include its limited scope (no assessment of psychosocial functioning of the individual) and the fact is it physician and not patient rated.

### 3.3.b Cantril's Self-Anchoring Life Satisfaction Scale (Cantril,1965)

This is single-item indicator of well-being. It can be used to assess satisfaction with life in general or specific topics, for example, health and economic status (McDowell and Newell, 1987). It has been used widely in population surveys (for example, Campbell et al., 1976; Andrews and Withey, 1976).

The scale consists of a picture of 9-rung ladder (see Table 3.3) with the top rung labelled 'the best life I could expect to have' and the bottom rung labelled 'the worst life I could expect to have'. Respondents are asked to place themselves on the ladder in relation to these two anchors. The wording of the instructions can vary depending on the research topic of interest, For example, if the investigator was interested in an individuals perception of their current health status the question may be phrased 'Where on the ladder would you place your current health'. By re-phrasing the questions the scale can be used to assess the individuals perceptions of the present, past or hopes for the future.

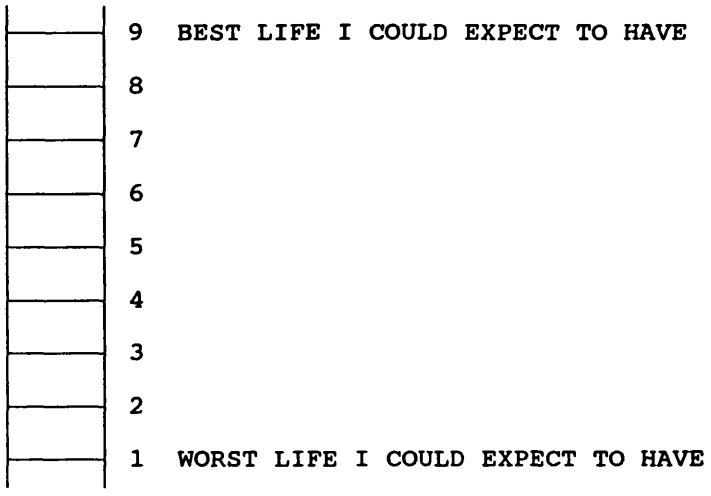
One of the main advantages of this scale is that it takes account of the individuals perceptions, attitudes and goals and allows assessment of the relative aspects of QOL. Other advantages include its simplicity, flexibility and wide usage (particularly in population surveys).

Lack of data relating to reliability and validity is the main disadvantage of this scale. The scale was originally used by Cantril (1965) without any formal validation and while Andrews and Withey (1976) attempted to formally validate the scale, the data is limited.

Table 3.2: The Karnofsky Performance Index

| Description | Scale % |
|---|---|
| Normal, no complaints | 100 |
| Able to carry on normal activities; minor signs or symptoms of disease | 90 |
| Normal activity with effort | 80 |
| Cares for self. Unable to carry on normal activity or to do active work | 70 |
| Requires occassional assistance, but able to care for most of his needs | 60 |
| Requires considerable assistance and frequent medical care | 50 |
| Disabled; requires special care and assistance | 40 |
| Severely disabled; hospitalisation indicated although death not imminent | 30 |
| Very sick. Hospitalisation necessary. Active supportive treatment necessary | 20 |
| Moribund | 10 |
| Dead | 0 |

Table 3.3: Cantril's Self-Anchoring Ladder



With regard to reliability, Andrews and Withey (1976) report an estimated average test-retest reliability of 0.70 (based on combined reliability estimates from several surveys in which the scale was given twice in the same interview). In addition, they report a two-year test-retest reliability of 0.40 in a community sample (rising to 0.47 for those not reporting any major changes in life circumstances). The long inter-test interval, however, raises serious questions about the validity of even doing this analysis. Andrews and Crandall (1976) investigated the validity of the Ladder Scale in 222 adults in Ohio, using the multitrait, multimethod approach. They report a median validity coefficient of 0.70.

Other disadvantages of this scale include the need to make the assumption that it provides measurements on an interval scale and the single-item judgements that are required to be made. It is possible that an individual will need to make judgements about an aspect of their life (eg economic/employment situation) in which they are happy with some areas, but not others (for example, being happy with job, but not pay).

Other examples of single-item indicators include the Delighted-Terrible Scale, the Faces Scale and the Circles Scale and these are reviewed by McDowell and Newell (1987).

### 3.3.c Linear Analogue Self Assessment Scales (Priestman and Baum, 1976)

Priestman and Baum (1976) developed their 25-item test to measure the impact of breast cancer and its treatment on QOL. The test covers four main areas: symptoms and effects of disease and treatment (10 items eg. pain, nausea); psychological effects (5 items, eg. anxiety, depression); physical ability (5 items eg. ability to do housework) and personal relationships (5 items).

Table 3.4 gives some examples of items from the LASA. Each item is represented by a 10cm line labelled at each end with the extremes of the experience being measured, for example:

Table 3.4: Examples of items from Priestman and Baum's LASA

DIFFICULTY WITH SLEEP

Most nights ——————————————— Never

FEELING OF WELL-BEING

Very bad ——————————————— Very good

RELATIONSHIP WITH PARTNER

Impossible ——————————————— Excellent

RELATIONSHIP WITH OTHER PEOPLE

Impossible ——————————————— Excellent

SEXUAL RELATIONSHIPS

Total loss ——————————————— Better than ever

DECISION MAKING

Impossible ——————————————— Excellent

ABILITY TO PERFORM HOUSEWORK

Impossible ——————————————— Better than ever

HAVE YOU HAD PAIN TODAY?

Not at all _____ Severe pain

The patient is asked to mark the line at a point which corresponds to his perception of the experience. Scoring is performed by calculating the distance (in cm) from the positive ('not at all') end.

While the simplicity of the LASA is attractive, there is little published data to support the reliability and validity of the scale. Priestman and Baum in their original 1976 paper report a 24 hour reliability coefficient of 0.87. This relates, however, to a shorter, 10 item LASA (incorporating the following indices: feeling of well-being, mood, level of activity, pain, nausea, appetite, ability to perform housework, social activities, level of anxiety and the question 'is treatment helping?). In addition the group tested was small and select (29 women with breast cancer) and the reliability findings confounded by change in situation between assessments (the first assessment was done at the clinic with a doctor present while the second was performed alone at home). The same study reports on the sensitivity of the LASA in discriminating those who showed an objective positive response to treatment from those who showed no response (response group n=6).

Another application of the LASA technique, again in cancer patients is that suggested by Selby et al.(1984). This comprehensive scale contains 32 items mainly derived from the Sickness Impact Profile (see Table 3.5 for example of items) and early work suggests good reliability and discriminant abilities (Fallowfield, 1990).

In theory, the LASA technique can be applied and adapted to any situation, however, it needs to be remembered that although there are reports to support the accuracy of LASA techniques in general (see Priestman and Baum, 1976) any newly developed LASA needs to be evaluated in the population for which it is to be used. Changes in the type of questions asked and the labels attached to the extremes of the line may alter the psychometric properties of the technique. Just using a

Table 3.5: Examples of items from Selby's LASA

Please score how you feel each of these aspects of your life was affected by the state of your health during today (past 24 hours)

DEPRESSION

extremely depressed ——————————————— not depressed at all

APPEARANCE OF YOUR BODY

extremely dissatisfied (because of the state of my health, disease or treatment) ——————————————— completely satisfactory for me at my age

FAMILY RELATIONSHIPS AND MARRIAGE/COHABITATION

extremely bad relationships because of the state of my health ——————————————— normal family life for me

HOUSEWORK

no housework because of the state of my health ——————————————— normal household duties for me

10cm line does not immediately confer reliability, validity and sensitivity to a scale!

The advantages and disadvantages of linear analogue scales have been discussed previously (this chapter). In relation to the Priestman and Baum model and its usefulness in patients with epilepsy there are two main disadvantages. First, the life domains covered are limited (the majority of items cover physical effects of treatment); second, published data on reliability and sensitivity is minimal, with available evidence limited to cancer patients. Similarly, the Selby LASA is still being developed and has been applied solely in cancer patients.

### 3.3.d Psychosocial Adjustment to Illness Scale (Morrow et al.,1978; Derogatis, 1986)

The Psychosocial Adjustment to Illness Scale (PAIS) was originally developed as a semi-structured interview, but a self-report version is also available (PAIS-SR). Fallowfield (1990) considers the PAIS to be 'one of the most impressive tests developed in recent years which could be used to evaluate quality of life in a variety of patient populations'.

The PAIS is a 45 item questionnaire which assesses adjustment to illness in seven domains: health care orientation (attitude/expectations of doctors and treatments), vocational environment (disruption to job performance, satisfaction with job and adjustment to work following illness), domestic environment (family relationships, communication and impact on finances), sexual relationships (quality, frequency, sexual satisfaction), extended family relationships (communication, interaction, degree of dependency), social environment (level of participation, level of interest) and psychological distress (anxiety, depression, guilt, hostility). Ratings are made on a 4-point scale (0-3) and summed to give scores for the 7 domains as well as an overall adjustment score based on the 45 items. Scores are converted to standardised T-scores (given in the PAIS handbook) which can be compared to published norms. Norms are available for the PAIS in four patient groups: lung cancer, renal dialysis, acute burns and hypertensive patients. In

addition, two normative groups of patients are available for the PAIS-SR: cardiac bypass and cancer patients (Derogatis, 1986). Table 3.6 gives examples of some of the items contained in the PAIS.

The internal consistency of the PAIS has been assessed in 2 patient groups (renal dialysis, n=269; lung cancer, n=89). Good reliability coefficients were generally seen for all PAIS domains (ranging from 0.63 to 0.93). One exception was seen for the extended family domain in the lung cancer group which have an internal reliability coefficient of only 0.12. Similarly high coefficients were noted for the PAIS-SR in a group of 61 patients with cardiac disease (coefficients ranged from 0.62 to 0.85 one exception being health orientation, r=0.47) (Derogatis, 1986). In addition, inter-rater reliability has been assessed in two studies. In the first study (Morrow et al., 1978), 37 patients with Hodgkins disease were used to assess the inter-rater reliability of 6 raters. Inter-rater reliability for the total adjustment score was high (r=0.83), but variable for the individual domains ranging from 0.33 (extended family relationships) to 0.82 (psychological distress). Derogatis (1986) reports an inter-rater reliability coefficient for the PAIS total score of 0.86 with the coefficients for the seven domains ranging from 0.56 (extended family) to 0.86 (sexual relationship). This second study was conducted in 17 patients with breast cancer. No published data relating to test-retest reliability is available for either the PAIS or the PAIS-SR.

The content validity of the PAIS was examined by a factor analysis based on assessments of 120 patients with lung cancer. Seven factors were identified which corresponded closely to the hypothesised structure of the PAIS (Derogatis, 1986). Construct validity has been examined by looking at the inter-relationships between the 7 domains in three clinical samples (two for the PAIS and one for the PAIS-SR). A consistent pattern of low correlations among domain scores with concomitant high correlations with total score is seen for all 3 groups. In relation to the PAIS, the mean correlation among domains was 0.33 among the lung cancer patients (n=120) and 0.10 among Hodgkins disease patients

Table 3.6: Example items from the PAIS

SECTION 1: HEALTH CARE ORIENTATION

How do you feel about the treatment you have been receiving for your present illness and the doctors who are treating you?

0 = very positive with high levels of confidence
1 = generally positive with some reservations
2 = somewhat negative with visible cynicism
3 = clearly negative with a lack of confidence and mistrust

SECTION 2: VOCATIONAL ENVIRONMENT

Have you had to change your basic goals regarding your job as a result of your illness?

0 = goals unchanged
1 = slight modification related to illness
2 = significant reduction in scope and comprehensiveness of goals
3 = marked modification or shift in goals

SECTION 3: DOMESTIC ENVIRONMENT

How would you characterise your relationship with your spouse?
0 = very good
1 = adequate
2 = somewhat inadequate
3 = markedly inadequate

SECTION 4: SEXUAL RELATIONSHIPS

Has there been any change in the pleasure or satisfaction you derive from sexual activities?

0 = no change in sexual satisfaction
1 = slight reduction in pleasure or satisfaction
2 = marked reduction in pleasure or satisfaction
3 = no sexual pleasure or satisfaction

SECTION 5: EXTENDED FAMILY RELATIONSHIPS

Do you depend on those members of your family for any help or assistance, partcularly since your illness?

0 = totally independent of extended family
1 = some dependency, consistent with degree of family commitment
2 = some dependency, beyond degree of family commitment
3 = marked dependency, beyond degree of family commitment

SECTION 6: SOCIAL ENVIRONMENTS

Have you maintained your interest in social activities since your illness (eg social clubs, church groups, going to the movies etc)?
0 = same level of interest as previously
1 = slightly less interest than before
2 = significantly less interest than before
3 = little or no interest remaining

SECTION 7: PSYCHOLOGICAL DISTRESS

Have you been feeling anxious or nervous recently?

0 = not at all
1 = mildly
2 = moderately
3 = markedly

Note: examples taken from semi-structured interview version described by Morrow et al (1978).

(n=37) while the PAIS-SR showed an average domain intercorrelation of 0.28 (148 kidney dialysis patients) (Morrow et al., 1978; Derogatis, 1986).

Morrow et al (1978) provide evidence of construct validity based on significant and expected correlations with external measures of the same trait (for example, the psychological distress domain correlated 0.51 with patients self-ratings on the State-Trait Anxiety Inventory and 0.49 with ratings on the Beck Depression Inventory). It should be noted, however, that although all correlations quoted were significant at the 0.05 level or higher, the actual correlations are not that high (ranging from 0.27 to 0.51). In addition, Derogatis (1986) provides data on the correlations between PAIS scores and other psychological test scores (global adjustment to illness scale (GAIS); SCL-90-R general severity index; affect balance scale index; patients attitudes, information and expectancies (PAIE) scale). A number of expected correlations were seen providing some evidence of convergent/divergent validity. Some evidence of the validity of the PAIS-SR total score and PAIS-SR psychological distress domain score is also available (Kaplan-DeNour, 1982). This study reported significant positive relationships between the PAIS-SR total score and the MACL, and between physician's ratings of psychological impairment and the Psychological Distress score on the PAIS-SR.

The predictive validity of the PAIS has been assessed in a study in which the scores of 120 patients screened as positive for lung cancer were compared with 86 patients who were screened negative. Statistically significant differences were seen for five of the seven domain scores and the PAIS total, with the positive group showing poorer adjustment (higher scores) (Derogatis, 1986). In addition, Kaplan-DeNour (1982) demonstrated the ability of the PAIS-SR to distinguish dialysis patients rated as 'good' and 'bad' adjusters by their physicians.

Advantages of this measure are its comprehensiveness and the availability of norms. Disadvantages include the time taken to complete the questionnaire (approximately 30 minutes) and the complexity of the scoring. In addition, no norms are

available for epilepsy patients. The PAIS does not attempt to address the comparative nature of QOL. although it does attempt to include expectation in relation to treatment. No information not currently available on test-retest reliability.

### 3.3.e Nottingham Health Profile (Hunt and McEwen, 1980; McEwen and McKenna, 1985)

The Nottingham Health Profile (NHP) was designed to measure perceived health problems and the extent to which these impinge on the everyday activities of the patient (Hunt, 1984). There are two parts to the questionnaire. Part I consists of 38 statements grouped into six areas of functioning: sleep (5 items), physical mobility (8 items), energy level (3 items), pain (8 items), emotional reactions (9 items) and social isolation (5 items). All statements require a yes or no response from the respondent. A weighted score is obtained for each of these areas with a high score indicating greater problems/difficulties. The weighting is patient-based (using Thurstone's paired comparisons technique conducted in 1,200 outpatient interviews). A simpler, unweighted scoring system is also used in which the number of affirmative responses in each area is counted (McDowell and Newell, 1987). Part II consists of seven statements relating to areas of life most often affected by health. Patients are asked (using a yes/no response format) whether their health is causing problems with their paid employment, social life, home life, looking after the home, interests and hobbies, sex life or holidays. Statements in Part II are scored one for an affirmative response and zero for a negative reply. Tables 3.7 and 3.8 contain the statements included in the Nottingham Health Profile (NHP).

A large amount of research has been undertaken to establish the reliability and validity of the NHP (Hunt, McEwen and McKenna, 1986). The face, content and criterion validity of the scale has been tested in a variety of populations including over 65's with differing clinical conditions (41 fit, 19 with no known illness, 49 with a variety of health and social problems, 54 chronically ill), GP

Table 3.7: Items included in Part I of the Nottingham Health Profile showing section to which item relates

Energy Level

I'm tired all the time
Everything is an effort
I soon run out of energy

Social Isolation

I feel lonely
finding it hard to make contact with people
I feel there is nobody I am close to
I feel I am a burden to people
I'm finding it hard to get on with people

Emotional Reactions

Things are getting me down
I've forgotten what it is like to enjoy myself
I'm feeling on edge
The days seem to drag
I lose my temper easily these days
I feel as if I'm losing control
Worry is keeping me awake at night
I feel that life is not worth living
I wake up feeling depressed

Sleep

I take tablets to help me sleep
I'm waking up in the early hours of the morning
I lie awake for most of the night
It takes me along time to get to sleep
I sleep badly at night

Pain

I have pain at night
I find it painful to change position
I'm in pain when I walk
I'm in pain when I'm standing
I'm in constant pain
I'm in pain when going up or I'm down stairs or steps
I'm in pain when I'm sitting
I have unbearable pain

Physical Mobility

I can walk about only indoors
I find it hard to bend
I'm unable to walk
I have trouble getting up and down stairs or steps
I find it hard to reach for things
I find it hard to dress myself
I find it hard to stand for long
I need help to walk about outside (eg walking aide or someone to support me)

Table 3.8: Items from Part II of the Nottingham Health Profile

Instructions

We would like you to think about the activities in your daily life which may be affected by your health problems. In the list below tick YES for each activity in your life which is being affected by your state of health. Tick NO for each activity which is not being affected or does not apply to you

IS YOUR PRESENT STATE OF HEALTH CAUSING PROBLEMS WITH YOUR...

1. JOB OF WORK
   (That is, paid employment)

2. LOOKING AFTER THE HOME
   (Examples: cleaning & cooking, repairs, odd jobs around the home etc.)

3. SOCIAL LIFE
   (Examples: going out, seeing friends, going to the pub etc.)

4. HOME LIFE
   (That is, relationships with other people in your home)

5. SEX LIFE

6. INTERESTS & HOBBIES
   (Examples: sports, arts and crafts, do-it-yourself etc.)

7. HOLIDAYS
   (Examples: summer or winter holidays, weekends away etc)

consulters and non-consulters (n=252), firemen (158), patients with peripheral vascular disease (n=93), patients with fractures (141 fractures, 141 controls; comparison of 2 assessments made 8 weeks apart), non-acute out-patients (n=157, 41 tested before and after minor surgery) (Hunt et al., 1980, McEwen, 1988). The NHP successfully discriminated between 'well' and 'ill' populations and was shown to be sensitive to changes in perceived health status following treatment.

Test-retest reliability was assessed in two groups of patients: 58 patients with osteoarthritis and 93 with peripheral vascular disease. The test-retest interval was 4 weeks for the osteoarthritis group and 8 weeks in the peripheral vascular disease group. Correlation coefficients for Part I ranged from 0.75 to 0.88 (Spearmans r) with a larger range evident for Part II statements (Cramers C, 0.44 to 0.89).

In addition, two studies have been conducted to establish population norms for this instrument: one conducted among 2192 patients randomly drawn from a GP population and the second based on 1753 employees in a large manufacturing organisation. These studies looked specifically at differences in NHP scores attributable to sex, age and social class.

In summary this is a brief, well-conceptualised and well-researched measurement tool with a number of advantages. It is acceptable, inexpensive, and easy to use and understand. There are, however, a number of drawbacks. Part I statements represent severe situations and may miss less severe, but nonetheless distressing, disabilities; zero scores cannot register improvement even if noticed by the patient; there is a heavy reliance on physical symptoms; it concentrates on negative aspects of health and; the weighted scoring of Part I can be cumbersome.

The main drawback to its use in patients with epilepsy is the large proportion of statements relating to physical problems (mobility, pain etc). Such concerns are not usually considered to predominate the life of the patient with epilepsy, who is more likely to experience difficulties with social and emotional aspects of functioning.

### 3.3.f Sickness Impact Profile (Bergner et al., 1981)

This scale was used in the current study and in reviewed in detail in Chapter 4 (Materials and Methods). A copy of the full scale can be found in the Appendix (Appendix 6).

In brief, this is a comprehensive, generic, 136-item scale covering 12 areas of functioning: sleep and rest, eating, work, home management, recreation and pastimes, ambulation, mobility, bodycare and movement, social interaction, alertness behaviour, emotional behaviour and communication. Patients are asked to check any item which describes them today and is related to their health. Scores are weighted then summed and transformed to a percentage score to provide individual category scores. In addition, composite scores of physical, psychosocial and overall functioning can be computed. The higher the score on the SIP, the more dysfunctional the patient.

This scale has been widely used in a variety of patient populations including chronic obstructive pulmonary disease (McSweeney et al., 1982), renal disease (Hart and Evans, 1987), arthritis (Bergner et al., 1981), low back pain (Deyo et al., 1986) and has been used to evaluate changes in health care delivery (Bergner, 1988). In addition it is well researched with a wealth of published data relating to reliability and validity (Bergner et al., 1976; Pollard et al., 1976; Carter et al., 1976. McDowell and Newell (1987) state: 'The SIP has been developed with exemplary care and thoroughness.....The reliability results are good, the validity findings promising and this scale is likely to become a standard against which to judge other methods. We have no hesitation in recommending its use in clinical and survey research.'

The extensive psychometric testing which has been conducted on this measure was one of the factors influencing the choice of this measure for inclusion in the current study. In addition, it provides a good coverage of cognitive, emotional and social aspects of functioning, areas likely to be of concern for the person with epilepsy.

### 3.3.g McMaster Health Index Questionnaire (Chambers, 1982)

The McMaster Health Index Questionnaire (MHIQ) is a 59 item questionnaire covering the three components of health outlined in the World Health Organisation definition of health - physical function, emotional function and social function. Item selection was based on 'experts' and adaptations of existing measures (for example, the Katz Activities of Daily Living scale and the Social Readjustment Rating Scales). Physical function is assessed by 24-items covering physical activities, mobility, self-care activities, communication (sight/hearing) and global physical function; the 25-item social function scale covers general well-being, work, social role performance, material welfare, family support and participation, friends support and participation and global social function; the emotional function scale comprises of 25-items assessing feelings of self-esteem, attitudes to personal relationships, thoughts about the future, critical life events and global emotional function. The MHIQ only contains 59 items as some items address both social and emotional function (Chambers, 1988).

The self-administered version of the test takes approximately 20 minutes to complete. Items are scored such that a 'good function' response is given a score of 1, while a 'poor function' response is given a score of 0. Index scores are calculated by summing the responses given to items within that category (Table 3.9 gives some examples of the scoring system for the MHIQ).

Two studies were conducted to establish the test-retest reliability of the 3 MHIQ indexes (physical function, emotional function, social function). The first, carried out on 30 physiotherapy outpatients, and using a 1 week test-retest interval reported correlations of 0.53 (physical index), 0.70 (emotional index) and 0.48 (social index). Higher correlations were seen in the second study involving 40 psychiatry outpatients (1 week test-retest correlations: physical index, 0.95; emotional index, 0.77; social index, 0.66).

Table 3.9: Example of items and scoring system used in MHIQ

| ITEM | ITEM SCORING | |
|---|---|---|
| | GOOD function Score = 1 | POOR function Score= 0 |
| Physical function items | | |
| Today, do you (or would you) have any difficulty at all with walking as far as a mile? | NO | YES, NO ANSWER |
| Today, do you (or would you) have any physical difficulty at all with undressing? | NO | YES, NO ANSWER |
| Do you have trouble hearing the radio or television? | NO, NEVER | YES, SOMETIMES YES ALWAYS, NO ANSWER |
| Social function items | | |
| What is your occupational status? | WORK F/T, WORK P/T, ON VACATION, STUDENT, HOUSEWIFE | RETIRED, ON SICK LEAVE NO ANSWER |
| How long has it been since you last had a holiday? | LESS THAN OR EQUAL TO 12 MONTHS | GREATER THAN 12 MONTHS |
| Has a friend visited you in the last week? | YES | NO, NO ANSWER |
| Emotional function items | | |
| I sometimes feel that my life is not very useful. | STRONGLY DISAGREE, DISAGREE | STRONGLY AGREE, NEUTRAL, NO ANSWER |
| During the last year have you separated from your spouse? | NO | YES, NO ANSWER |
| During the last year have you retired from work? | NO | YES, NO ANSWER |

The validity of the MHIQ has been assessed in a variety of populations and studies. All three scales have been shown to correlate with global assessments made by health professionals Chambers, 1982). In patients with rheumatoid disease (n=4)0), the physical function index has been shown to correlate with observed performance assessed by occupational therapists (Chambers et al., 1982) and with rheumatologists assessment of clinical/biological indicators of function (eg active joint count, duration of morning stiffness) (Chambers, 1988). As hypothesised, the emotional and social indices did not correlate with the clinical/biological indicators. While the validity of the physical index is reasonably well established, evidence for the validity of the emotional and social indices is rarer. The evidence that is provided relates to comparisons of the three MHIQ indices of different patient groups and whether or not these follow certain hypotheses. In a comparison of physiotherapy outpatients (n=96) and psychiatric outpatients (n=40) the physical index score was significantly higher in the psychiatric population (higher score indicates better function) while the emotional and social indices were higher in the physiotherapy group. This is in line with expectations and thus provides some evidence of validity. Similarly, expected differences were seen comparing 4 groups of patients with differing degrees of illness (physiotherapy patients, respiratory disease patients, long term diabetics and general medical patients). The hypotheses that were supported were: (1) higher physical function in general medical patients than the other three groups; (2) lower emotional function in general medical patients than the other groups (this hypothesis was based on the premise that 50% of GP patients present with emotional problems) and (3) poorer social function in patients cared for at home (respiratory disease and long term diabetic groups).

The sensitivity of the physical index score was assessed in a physiotherapy outpatient group (n=40) who completed the MHIQ on 4 separate occasions:study entry (Time I), one week post study entry (Time II), discharge from clinic (Time III) and one week post-discharge (Time IV). No change in status was expected between Times I and II or Times III and IV, with a

change in status expected between Times II and III. The MHIQ physical index scores reflected these hypotheses, thus providing some evidence of sensitivity (Chambers et al., 1987). It is recognised that further work is need to determine the sensitivity of the social and emotional index scores (Chambers, 1988).

In summary, the MHIQ appears to be a comprehensive measure, applicable to a wide range of patient populations. The lack of psychometric data relating to the social and emotional indices is a matter of concern for the use of this instrument in an epilepsy population as these are the areas most likely to be affected in this patient group.

### 3.3.h Washington Psychosocial Seizure Inventory (Dodrill et al., 1980)

The goal of the Washington Psychosocial Seizure Inventory (WPSI) is to provide 'an economic, systematic and objective evaluation of the extent of psychosocial problems in areas important for epileptics' (Dodrill et al., 1980). However, the WPSI is not strictly a QOL measure. It is included here as it is one of the few scales developed specifically for use in patients with epilepsy and it addresses the impact of the illness on the patients psychosocial functioning. In addition, it has been widely used (Batzel et al., 1980; Dodrill, 1980a; Dodrill, 1980b; Dodrill, 1983; Dodrill and Clemmons, 1984; Dodrill, Beier et al., 1984; Dodrill, Breyer et al., 1984; Flanagan and Beran, 1985; Fraser et al., 1986; Tan, 1986; Dodrill, 1986; Warner et al., 1989).

The WPSI is a 132-item questionnaire covering 7 areas of functioning: family background, emotional adjustment, interpersonal adjustment, vocational adjustment, financial status, adjustment to seizures and medical management. Examples of questions from each area can be found in Table 3.10. Each item requires a 'Yes' or 'No' response about the self-perceived usual feelings and actions of the respondent. An overall psychosocial functioning score can be calculated. In addition 3 validity scales are included (number left blank scale; lie scale; rare item scale). These scales were designed to determine the acceptability of any completed WPSI. It is

Table 3.10: Example items from WPSI

| AREA | ITEM |
|---|---|
| Family Background | Did you feel secure in the home in which you grew up?<br>As a child, did you have trouble making friends? |
| Emotional Adjustment | Are you generally free from depression?<br>Are you often tense and anxious?<br>Are you usually able to think clearly? |
| Interpersonal Adjustment | Do you have trouble meeting people?<br>Do you enjoy social gatherings?<br>Do you feel at ease around people of the opposite sex? |
| Vocational Adjustment | Have you ever lost a job because of your seizures?<br>Are you satisfied with your employment situation?<br>Is transportation a problem? |
| Financial Status | Do you have sufficient money for basic needs?<br>Do you feel financially secure?<br>Can you afford your present living arrangement? |
| Adjustment to Seizures | Do you feel resentful that you have seizures?<br>Are you comfortable going out despite possible seizures?<br>Do you have trouble accepting your seizure problem? |
| Medicine and Medical Management | Do you like your doctor?<br>Do you feel your doctor really cares about you as a person?<br>Do you feel your seizures are being controlled as well as they can be?<br>Do you frequently have trouble remembering to take your medications? |

recommended that any completed inventory is invalid if more than 10% of items are left blank (that is, not completed), if the lie scale score is greater than 4 and if more than 5 rare items are endorsed (17 rare items are identified based on those items endorsed by less than 15% of patients in validation studies). A profile form is available onto which the raw scores for each area are plotted. The profile indicates how the respondent is functioning in relation to 4 regions: Region 1, no significant problems; Region 2, possible problems, but of limited significance; Region 3, distinct difficulties with definite adjustment significance and; Region 4, severe problems having a striking impact upon adjustment. These regions were based on the professional ratings for each area (and therefore do not allow an assessment of how the respondent feels an area is affected). An Adolescent Psychosocial Seizure Inventory (APSI, Batzel et al., 1987; Batzel et al., 1988) and a Spanish translation of the WPSI (Tiberia and Froman, 1986) are also available.

Internal reliability of the WPSI was assessed in 127 patients using the split-half method. Coefficients were generally high ranging from 0.92 (emotional adjustment) to 0.68 (medical management). An exception was the Rare Items Validity Scale with a coefficient of 0.37. Test-retest reliability was assessed in a sub-group (n=21) who completed the WPSI on two occasions with an interval of 30 days. For the clinical scales test-retest coefficients ranged from 0.66 (medical management) to 0.87 (financial status). The validity scales showed lower correlations (no blank, 0.28; lie scale, 0.58; rare items, 0.58) (Dodrill et al., 1980).

The validity of all WPSI scales was measured by the association between the WPSI scores and professional ratings (n=127). Correlations were high, ranging from 0.58 (medical management) to 0.73 (overall psychosocial functioning) (Dodrill et al., 1980).

There appears to be little published evidence of the sensitivity of the WPSI in detecting change over time. Apart from the 1980 publication, there does not appear to have been much published work conducted to provide additional evidence of the psychometric properties of the WPSI. This is surprising

in view of the wide use of this scale to define psychosocial problems in patients with epilepsy (Dodrill, 1983; Dodrill, Breyer et al., 1984; Dodrill, Beier et al., 1984; Tan, 1986) and to examine the influence of epilepsy-related and other variables to psychosocial functioning (eg. Dodrill, 1984; Dodrill, 1986). Some of the studies do provide further evidence of the validity of the WPSI, but this is not done in any systematic manner. For example, Batzel et al. (1980) demonstrate the ability of the vocational adjustment scale to differentiate between fully employed, underemployed and unemployed groups of people with epilepsy. This supports the validity of this scale of the WPSI.

While the WPSI covers many of the areas of life functioning that are considered important to the assessment of QOL, it does not attempt to evaluate the subjective nature of the ability to function (or not) within these areas and is thus not acceptable as a true measure of QOL. As Barofsky (1984) succinctly states: 'if one uses the definition of quality that Donabedian proposes, then the task for someone doing a quality of life assessment is to compare the patients current status with some ideal state. This judgement task is different from what is ordinarily asked of patients in most psychosocial assessments. As a result, psychosocial assessments are not necessarily quality of life assessments'. The WPSI attempts to objectively define psychosocial problems in patients with epilepsy. While it purports to be based on a patients self-perceptions of usual feeling and behaviours (Dodrill et al., 1980), it does not allow the patient to subjectively evaluate the impact that their psychosocial functioning/abilities have on their day to day lives or QOL.

### 3.3.i New Scales

Since this research project was initiated there have been a number of interesting QOL instruments developed, particularly in the epilepsy realm. While these were not available for use at the time, a review of current measures would be incomplete without a mention of these more recent additions to the armoury of QOL assessment methods.

Within the field of epilepsy, three groups of workers (1 in Britain and 2 in the United States) have been developing

QOL scales aimed specifically at patients with epilepsy. The Liverpool initiative (Baker, Smith et al, 1993) have adopted a battery approach incorporating both existing and specifically developed measures. The QOL model employed by this group incorporates physical, social and psychological aspects of the individual. Three novel scales have been developed: a Seizure Severity Scale (Smith et al., 1991; Baker et al., 1991), an Impact of Epilepsy Scale (Jacoby et al., 1993) and a Life Fulfilment Scale (Baker, Jacoby et al., 1993). This approach has been successfully used to examine the effects of antiepileptic treatment of the quality of life of patients with epilepsy (Smith et al., 1993). This approach has a number of advantages: 1) it has been developed and tested specifically on patients with epilepsy; 2) it has been developed in Britain; 3) the Life Fulfilment Scale attempts to incorporate an assessment of the patients 'ideal' life situation. On the negative side the use of a battery of tests precludes an individualised assessment of areas of importance and it makes no attempt to address the comparative nature of the QOL concept (for example, comparing current situation with past abilities or peer group).

The Epilepsy Surgery Inventory (ESI-55, Vickrey et al., 1992; Vickrey, 1993) has been developed in the USA specifically to assess changes in QOL following epilepsy surgery. It is a self-report measure covering 11 dimensions of health related QOL. It consists of a generic core of 35 items (covering 8 dimensions: general health perceptions, energy/fatigue, social function, emotional well-being, role limitations due to emotional problems, physical function, role limitations due to physical problems, pain) based on the RAND 36-item Health Survey (Ware and Sherbourne, 1992). This is supplemented by 19 epilepsy-specific items covering 3 dimensions (cognitive function, role limitations due to memory problems and overall QOL). In addition, the scale includes 1 item relating to change in health.

The Quality of Life in Epilepsy (QOLIE) project is a USA-based, multicentre study which began in late 1991 (Perrine, 1993). Its aim was to develop and validate an epilepsy specific inventory for patients with mild to moderate

epilepsy. The test battery is based on the EPI-55, but expanded to have a broader application. It consists of 98 items, with the RAND 36-item Health Survey forming a generic core to which epilepsy-specific items have been added (based on a literature review and expert opinion as to the areas of importance to people with mild to moderate epilepsy). The epilepsy-specific items added cover 10 dimensions: seizure specific health perceptions, worry about seizures, attention and concentration, memory, language, working and driving limitations, medication effects, social support, social isolation and overall QOL.

In addition, a number of scales have been developed which attempt to address the individual nature of QOL and, although not specifically designed for patients with epilepsy, warrant a mention here. The first of these, SBQOL (Dunbar and Stoker, 1992) uses a limited application of repertory grid techniques and was developed primarily to assess QOL in psychiatric patients. 28 items are included covering the following domains: sense of psychic well-being, physical well-being (particularly pain and mobility), social relationships, activities/hobbies/interests; mood, locus of control, sexual function, work/employment, religion and finances. Patients are asked to rate (on a digitalised visual analogue scale) their current situation (self-now) and their ideal situation (ideal-self). Scoring is based on comparing these two states.

An interesting approach to assessing individualised QOL based on Judgement Analysis has been developed in Ireland (McGee et al., 1991). The method uses five patient-elicited areas of importance to QOL (ELICITED CUES) and 5 provided areas (PROVIDED CUES: physical function, emotional function, social function, living conditions, general health). Patients are asked to make judgements about the QOL of hypothetical scenarios based on these areas. A visual analogue scale is used with the ends labelled 'as good as it could possibly be' and 'as bad as it could possibly be'. This method has been employed in a number of populations including healthy volunteers, gastroenterology patients and rheumatoid arthritis patients.

The WHOQOL is an initiative by the World Health Organisation to produce a cross-culturally valid, generic QOL instrument (Orley, 1991; Orley, 1992; Sartorius, 1993). It is envisaged that a core instrument will be supplemented by modules designed for use with specific groups (for example, cancer patients, refugees, the elderly, specific diseases). The proposed structure of the WHOQOL incorporates 5 domains: physical health (general health, pain and discomfort, energy and fatigue, sexual activity, sleep and rest), psychological health (positive affect, sensory functions, thinking, learning, memory, concentration, self-esteem, bodily-image and appearance, negative affect), level of independence (mobility, ADL, dependence of substances, communication capacity, work capacity), social relationships (intimacy, loving relationships, practical social support, activities as a provider/supporter), environment (physical safety and security, home environment, work satisfaction, financial resources, accessability and quality to health and social care, opportunities for acquiring new information and skills, participation in recreation/leisure activities, physical environment (pollution, noise, traffic, climate), transport). Other domains which may be incorporated include spirituality, religion and personal beliefs. A pilot version is currently undergoing testing in field centres in Australia, Croatia, India, Netherlands, Panama, Russia, Thailand, Britain, United States and Zimbabwe. The final version is expected to be completed by 1994.

### 3.3.j Quality Adjusted Life Years (QALY's)

The development of the concept of quality adjusted life years (QALY's) represents the health economists approach to the assessment of QOL. This method of assessing QOL has no direct relevance to the current, clinically-orientated study and will not be discussed in detail, however, no review of QOL measurement techniques would be complete without some reference to QALY's. QALY's represent attempts to incorporate QOL information into economic formulae in an endeavour to provide evidence of the cost-effectiveness or cost-benefit of medical interventions and to plan resource allocations. Much

of this work is based on utility or decision theory and well-known measures include the time trade-offs method (TTO) (Torrance, 1986), the Quality of Well-Being Scale (formerly the Index of Well-Being Scale (Kaplan, Bush and Berry, 1976) and the Rosser Valuation Index (Rosser and Kind, 1978; Kind, Rosser and Williams, 1982). Readers are guided to Fallowfield (1990, chapter 9) and Teeling-Smith (1988) 'Measuring Health: A Practical Approach' for further details of this approach to assessing QOL.

# CHAPTER 4
# MATERIALS AND METHODS

## 4.1 PURPOSE OF THE INVESTIGATION

A review of currently available measures of quality of life highlighted various shortcomings, particularly in relation to the assessment of patients with epilepsy. At a general level, a major criticism of these assessment methods is that they neglect the patients' own perceptions of their quality of life. Even though the majority of the measures are self-administered, the scoring method is often based on weights assigned by 'expert judges'. No, or little, consideration is given to the importance that the individual themselves place on their ability to perform (or not perform) certain functions. Another problem is the limited range of areas of functioning assessed by many of these measures. Although in the literature a broad consensus is evident regarding the life domains pertinent to the assessment of quality of life (generally, physical functioning, cognitive abilities, emotional status, social functioning and economic/employment status) very few of the assessment procedures actually cover all these aspects (see Table 4.1).

The issue of the transferability of questionnaires developed in one cultural setting to another culture is also of importance. Even between English speaking cultures, for example the United States and Great Britain, population differences in behaviour and attitudes exist which may limit the value of questionnaires developed, for example, in the US in Britain and vice versa.

Where translations are performed, these are often done ad hoc with little or no information as to whether or not the translation conveys the same question. The psychometric properties (reliability, validity) may also differ across cultures and it is therefore advisable to re-determine these data in the culture in which the measure is to be used.

Finally, many of the measures have been developed with specific disease groups in mind, for example cancer patients and hypertensives, in which the impact of illness is fairly homogeneous and it is possible to determine common areas of concern for that particular patient group. Epilepsy is an illness which displays a great heterogeneity both in the form is takes (as evidenced by the numerous epilepsy syndromes and

Table 4.1: Examples of currently available measures of QOL and areas of functioning covered.

| | Physical | Cognitive | Affective | Social | Econ/Work |
|---|---|---|---|---|---|
| KPI | + | - | - | - | - |
| HAD | - | - | + | - | - |
| MHIQ | + | - | + | + | - |
| NHP | + | - | + | + | + |
| SIP | + | + | + | + | + |

KPI, Karnofsky Performance Index; HAD, Hospital Anxiety and Depression Scale; MHIQ, McMaster Health Index Questionnaire; NHP, Nottingham Health Profile; SIP, Sickness Impact Profile.

seizure types documented) and the impact it has on the life of the individual. The impact of epilepsy on quality of life may differ for the patient with absence seizures compared with the patient with generalised tonic-clonic seizures. Even within the same seizure group, differences in frequency and severity may lead to differences in the way in which epilepsy affects the patients' everyday life. Patients with epilepsy present with a variety of psychological, social and medical problems and it is thus difficult to determine a comprehensive list of areas of common concern to all patients with epilepsy. While possible to a degree, such an approach would be likely to lead to the exclusion of concerns of importance to many individuals due to the large population variance seen in patients with epilepsy.

It was felt that there was a clear need for a quality of life assessment tool which was specifically designed to address issues of importance to the patient with epilepsy; and which was validated for use in this group. In particular, it was considered that the method needed to be as individualised as possible to enable the heterogeneity of concerns of patients with epilepsy to be addressed. More specifically, the study had three main aims:

1. To develop a method for assessing quality of life (QOL) in patients with epilepsy, based on patients' own perceptions of their health status and its impact on their lives.
2. To assess the feasibility and practicality of the method in this group of patients.
3. To determine the psychometric properties of the method, including reliability, validity (face, content, construct) and sensitivity (discriminant ability).

Three studies were conducted to address these issues.

## 4.2. STUDY 1: EPILEPSY I

### 4.2.a Aims

The aims of the first investigation were:

1. To develop and refine, based on practical experience, a method for assessing quality of life in patients with epilepsy.

2. To assess the feasibility and practical application of the technique in this patient population.
3. To investigate the temporal stability of the method in a group of patients followed prospectively over a 6 month period.
4. To provide preliminary data regarding the issue of sensitivity. It was hypothesised that life events may be important determinants of quality of life and that patients experiencing significant life events during the study period would differ from those that did not in terms of their assessment of quality of life.
5. To determine the influence of epilepsy-related variables, including seizures and medication on quality of life assessments.

4.2.b **Subjects**

The majority of subjects were recruited from patients at the Residential Centre of the Chalfont Centre for Epilepsy in Buckinghamshire. In addition, a number of subjects were recruited from an independent hostel, close to the centre. The experimenter visited the hostel and each of the houses on the Epilepsy Centre, holding group meetings with the residents. During these meetings the nature and purpose of the study were explained and all individuals expressing a wish to participate were entered into the study. In addition, those expressing an interest in participating in the study were given a Subject Information Leaflet detailing the nature and purpose of the study and what would be expected from people wishing to participate in the study (copy in Appendix 1). Written, informed consent was obtained from all subjects. All participants were informed of their right to withdraw from the study at any time. Patients were excluded from the study if they were unwilling or unable to participate in the study or if they had a progressive neurological disorder.

### 4.2.c Measures

### 4.2.c.i Development of the Quality of Life Assessment Schedule (QOLAS)

The method developed for this work is based on repertory grid technique (Fransella and Bannister, 1977). This methodology provides a practical, standardised and objective way of assessing people's perceptions of QOL.

Repertory Grid Technique

Repertory Grid Technique (RGT) is the methodological component of Personal Construct Theory, a theory of personality proposed by George Kelly in the 1950's (Kelly, 1955). The fundamental postulate of this theory is that 'a person's processes are psychologically channelized by the ways in which he anticipates events' (Kelly, 1955). According to Kelly, man can be viewed as a scientist, who formulates theories or hypotheses relating to himself and the world he inhabits. These theories are based on his personal construction or interpretation of experienced events and thus form a, 'personal construct system'. The philosophical underpinning of the theory is 'constructive alternativism' which assumes that 'all of our present interpretations of the universe are subject to revision or replacement' (Kelly, 1955). Thus a man's personal construct system is not seen as a static phenomena but rather a dynamic process in which he makes sense of his experiences by continually testing and revising his hypotheses. As a scientist, his aim is prediction and the purpose of his construct system is to be able to predict and anticipate future 'real' events. In addition, Kelly proposes 11 corollaries relating to the nature of personal construct systems (see Table 4.2).

Repertory grid technique attempts to objectively explore and measure an individuals construct system. There are three major components of the technique: elements, constructs and the repertory grid itself.

**1. Elements.** These define the area of construing to be studied. If we wished to study the individuals construing of interpersonal relationships, the elements are likely to be people. If, however, we were interested in his construction

Table 4.2: Summary of Kelly's Personal Construct Theory

| | |
|---|---|
| A. | Fundamental Postulate: 'A person's processes are psychologically channelized by the ways in which he anticipates events'. |
| B. | Construction corollary: 'A person anticipates events by construing their replications'. |
| C. | Individuality corollary: 'Persons differ from each other in their construction of events'. |
| D. | Organization corollary: 'Each person characteristically evolves, for his convenience in anticipating events, a construction system embracing ordinal relationships between constructs'. |
| E. | Dichotomy corollary: 'A person's construction system is composed of a finite number of dichotomous constructs'. |
| F. | Choice corollary: 'A person chooses for himself that alternative in a dichotomized construct through which he anticipates the greater possibility for extension and definition of his system'. |
| G. | Range corollary: 'A construct is convenient for the anticipation of a finite range of events only'. |
| H. | Experience corollary: 'A person's construct system varies as he successively construes the replications of events'. |
| I. | Modulation corollary: 'The variation in a person's construction system is limited by the permeability of the constructs within whose range of convenience the variants lies'. |
| J. | Fragmentation corollary: 'A person may successively employ a variety of construction sub-systems which are inferentially incompatible with each other'. |
| K. | Sociality corollary: 'To the extent that one person construes the construction processes of another, he may play a role in the social processes involving the other person'. |

From Kelly (1955)

of illness, the elements may be different diseases.

**2. Constructs.** Kelly defines a construct as 'a way in which some things are construed as being alike and yet different from others'. Thus, a construct is simply a way in which the individual groups and differentiates between the elements.

**3. Repertory grid.** In the Oxford English Dictionary 'repertory' is defined as 'a place for finding something, a store of information'. Similarly, in repertory grid technique, the grid itself is a linking mechanism in which the mathematical value assigned to each construct for each element is collated. A basic assumption of the technique is that the mathematical relationships within the repertory grid reflect psychological relationships within the persons construing system.

Application of RGT to the assessment of quality of life

Four major concepts underpin the method (QOLAS) that has been developed for the assessment of quality of life in patients with epilepsy. First, it is proposed that,in general terms, 5 areas important to quality of life can be defined. These are physical functioning, cognitive abilities, emotional status, social functioning and economic/employment status. Secondly, it is recognised that within these general areas, specific items of importance will vary from individual to individual. Thirdly, it is hypothesised that QOL is a function of levels of expectation. Thus, it is the discrepancy between current life situation and expectations that is important in determining an individual's QOL, not simply how they are at present. Fourthly, it is suggested that QOL is a comparative phenomena. In judging their QOL, an individual makes comparisons of their current life situation in relation to other times and people in their lives.

Choice of elements

Based on these proposals, 10 'elements' considered appropriate to the assessment of quality of life (QOL) were chosen by the experimenter. These represent various situations and people in the patients life (see Table 4.3)

Table 4.3: Elements used in QOLAS (Study 1)

| Abbreviation | Details |
|---|---|
| NOW | As you are now |
| BEFORE | As you were before developing epilepsy OR how you imagine life would be without epilepsy |
| LIKE | As you would like to be |
| EXPECT | As you expect to be in six months time |
| AGE 25 | As you were (or expect to be) at age 25 |
| AGE 50 | As you expect to be (or were) at age 50 |
| AGE 75 | As you expect to be at age 75 |
| FRIEND | As a close friend is now |
| BEST | As someone with the best life would be |
| WORST | As someone with the worst life would be |

Construct elicitation

The constructs (or areas of importance to quality of life (QOL)) are individual to each patient and were elicited through a semi-structured interview (details in Appendix 2). During the interview, the elements were presented in groups of three (triads) and the patients were asked: "think of a way in which two of these are alike and different from the third in terms of their quality of life". For example, in comparing the elements 'as you are now', 'as you were before having epilepsy' and 'a close friend' a patient may respond "my friend and I both have epilepsy, whereas before I didn't". 'Having epilepsy' is a way in which the patient differentiates the elements and is thus termed a 'construct'. Where patients had difficulties with this procedure the elements were presented in pairs (dyads) and similarities and differences between the pair of elements discussed. This procedure was repeated until at minimum of ten 'constructs' had been elicited (two for each of the five main areas of physical functioning, cognitive ability, emotional status, social functioning and economic/employment status). Patients were guided during the interview to elicit constructs within these five areas by rephrasing the question asked. Thus, to elicit a construct in the physical domain they would be asked: "think of a way in which two of these (elements) are similar and different from the third in terms of their physical abilities". Similarly, to elicit a construct relating to social functioning, the patient would be asked: "think of a way in which two of these (elements) are similar and different from the third in terms of their social life and relationships with family and friends".

Mode of responding

Patients rated each element on each construct using a 100-mm, horizontal, visual analogue scale anchored by 'No problem' and 'A severe problem'. The position of the anchored ends was randomly reversed to discourage respondents from establishing a pattern of responding. The score was calculated as the distance in mm from the 'Severe problem' end of the scale. Thus a score of 100 indicated 'No problem' and 0 'A severe problem'.

During the course of the study, however, it became apparent that a significant number of patients had difficulties in understanding this method of rating and thus it was changed to a 10-item, dashed line visual analogue scale. In addition, the scoring method was reversed such that 'No problem' was represented by a score of 1 and 'A severe problem' by a score of 10. It seemed logical that a higher score should indicate a greater degree of problem. A copy of the QOLAS used in Study 1 can be found in Appendix 3.

4.2.c.ii **Intellectual functioning**

Details of the intellectual ability of all patients were obtained from Wechsler Adult Intelligence Scale-Revised (WAIS-R, Wechsler, 1981) assessments performed by either the Chalfont Centre psychologist or an independent researcher, neither of whom were involved in the assessment of QOL in these patients. All IQ assessments had been performed within 1 year of entry to the study.

4.2.c.iii **Life events**

The occurrence of life events or any changes in the individuals situation are likely to influence their assessment of quality of life and it was felt that this was an important factor which needed to be explored. Study 1 was primarily concerned with assessing the practicability of using this novel methodology in patients with epilepsy and thus no formal, objective method of assessing life events was employed. Patients, however, were questioned informally at each visit to determine the occurrence of any major changes in their lives since their previous visit. At their first assessment patients were asked if any major life events had occurred during the six months prior to study entry. It was felt that any significant life event should be to the fore of the patients' mind and would be elicited upon such informal questioning. Details of the life events reported by this group can be found in Appendix 4.

4.2.c.iv **Epilepsy variables**

Seizures were classified by an independent observer, based on seizure descriptions and EEG findings. Seizures were recorded

prospectively during the study by patients and trained staff in seizure calendars. The number and type of seizure were recorded on a daily basis. The number of seizures in the 6 months prior to study entry were determined retrospectively from the Epilepsy Centre seizure calendars. This time period was chosen as seizure rate is open to random fluctuations and a long time base (6 months) should provide a more accurate picture of weekly or monthly seizure rate. Recent EEGs (performed within 3 years of entry to the study) were classified, according to the site of activity, by an independent observer:

1 = Left sided abnormality
2 = Right sided abnormality
3 = Bilateral, but independent activity
4 = Generalised activity

4.2.d **Study design**

A repeated measures design was employed in which patients were assessed on four occasions over a six month period: baseline (S1), 1 month (S2), 3 months (S3) and 6 months (S4).

4.2.e **Procedure**

The initial interview was of a semi-structured format in which basic demographic details and information relating to the patients epilepsy were obtained. In addition, the areas of importance to their quality of life, which would form the basis of the individualised quality of life assessment schedule (QOLAS), were elicited by the triadic/dyadic techniques described previously. The baseline (S1) assessment of quality of life took place approximately 1 week following the initial interview.

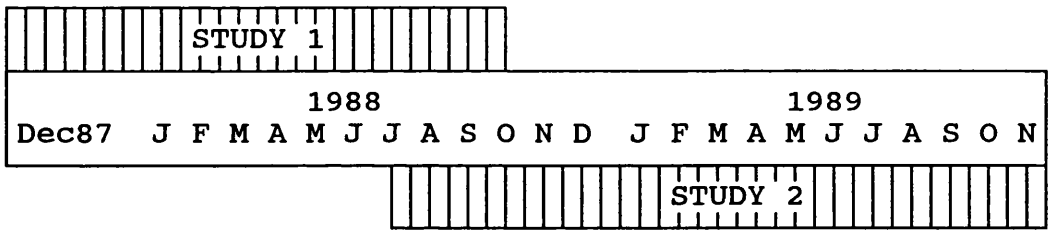
All questionnaires were completed by the patients themselves under the supervision of the experimenter, except for cases where a disability hindered the patient in doing so. In such cases the questionnaires were interviewer-administered. Care was taken to standardise, as far as possible, the responses given in reply to questions from the subjects thus reducing interviewer bias. Patients were assessed at the same time of day by the same interviewer (AM)

throughout the study. No patient was seen within 24 hours of a seizure. Each session lasted approximately 1 hour.

## 4.3 STUDY 2: EPILEPSY II

This study was a continuation and expansion of Study I. The feasibility of using the method (QOLAS) in patients with epilepsy had been established in Study 1 and thus Study 2 was set up with the intention of extending the available information regarding the psychometric properties of the instrument. The two epilepsy studies were run in parallel (see Table 4.4).

Table 4.4: Timing of studies




A number of Study 1 patients completed some of the additional questionnaires employed in Study 2, namely the Sickness Impact Profile, the Mood Adjective Checklist and the Life Events Scale (See Study 2 (Measures) for details of these questionnaires) at follow-up assessments. No Study 1 patients completed these questionnaires at session 1. These data were collected to increase the number of cases in which correlational analyses between the measures could be performed (assessing convergent/divergent validity).

### 4.3.a Aims

The specific aims of Study 2 were:

1. To provide further information on the temporal stability of the technique.
2. To provide information regarding the validity of the measure (QOLAS), specifically:
   * face validity. Does it have good face validity with both patients and health care professionals?.

* content validity. Does it contain meaningful items?.
* construct validity. To what extent does it capture information similar to that found with currently available measures of QOL (convergent validity)? Does it capture information different from current methods of assessment (divergent validity)?

3. To examine the link between life events and QOL.
4. To provide information regarding the reliability and validity of the scales chosen to validate the QOLAS (SIP, MACL-D, LES). These measures have been standardised and validated in various groups including patient populations and students, however, the psychometric properties of these instruments when used in a population with epilepsy is unknown.

### 4.3.b Subjects

All patients were residents at the Chalfont Centre for Epilepsy. Recruitment and inclusion/exclusion criterion were as for Study 1.

### 4.3.c Measures

#### 4.3.c.i Quality of Life Assessment Schedule (QOLAS)

A review of the methodology resulted in several changes in the QOLAS between Study 1 and Study 2. A copy of the revised QOLAS can be found in Appendix 5).

First, the rating method was simplified by changing from a 10-item dashed analogue scale to a 5-item rating scale ranging from 'Not a problem' to 'It could not be worse'.

Secondly, three of the elements used in the original version (AGE 25, AGE 50 and AGE 75) were changed to 5 YEARS AGO, IN 5 YEARS TIME, IN 10 YEARS TIME. These were then subsequently revised to MOTHER, FATHER, AS OTHERS SEE YOU. These changes were made as it was found that patients had difficulties in making judgements about hypothetical situations (for example, how do you think you will be at the age of 75 or in 10 years time). On the premise that quality of life is a comparative phenomena in which a person's view of their own life situation in relation to important others (for example, family members and peers) is a salient factor in

their overall judgement of quality of life, it was considered that the elements (MOTHER, FATHER, AS OTHERS SEE YOU) might be more appropriate. The remaining seven elements (NOW, BEFORE, EXPECT, LIKE, FRIEND, BEST, WORST) were unchanged between studies.

Thirdly, the number of constructs elicited was increased from ten to fifteen. During the construct elicitation procedure it was found that in several instances a patient would spontaneously report many areas of importance in one specific life domain, for example social functioning, while none were forthcoming in other domains. By restricting each patient to two items within each domain and forcing them to choose two within a domain that may not have been of particular relevance to them, it was felt that items of importance may be excluded. In addition, constructs were sometimes elicited which did not readily fit into any of the five domains considered (physical, cognitive, emotional, social, economic/employment), for example, having faith in God. Thus, in Study 2, five free constructs were added to the questionnaire, allowing patients more freedom in the items of importance chosen. Full details of the changes made during the development of the test instrument can be found in Table 4.5.

4.3.c.ii **Sickness Impact Profile (SIP) (Bergner et al., 1981)**
This is a general health status questionnaire containing 136 statements about health-related dysfunction and covering 12 areas of functioning: ambulation, bodycare and movement, alertness behaviour, social interaction, emotional behaviour, communication, sleep and rest, eating, work, household management and recreation/pastimes. Patients are asked to read the statements and endorse or tick only those statements that describe them at present and are related to their health. A scaled score is assigned to each item, based on the judgement of 25 'experts' who rated each SIP item on a 15-point scale of dysfunction. Percentage disability scores for each category are calculated by summing the scale values of all items checked in that category, dividing this sum by the maximum possible score for that category and multiplying the obtained quotient by 100. A score of 100 indicates maximal dysfunction.

Table 4.5: Details of the development of the Quality of Life Assessment Schedule in patients with epilepsy.

| Study | Patient numbers | Number of constructs | Rating method | Elements |
|---|---|---|---|---|
| 1 | 1-10 | 10 | 100 VAS | AGE 25<br>AGE 50<br>AGE 75 |
| | 11-24 | 10 | 1-10 VAS | AGE 25<br>AGE 50<br>AGE 75 |
| 2 | 25-31 | 10 | 1-5 LIKERT | -5 YEARS<br>+5 YEARS<br>+10 YEARS |
| | 32-50 | 15 | 1-5 LIKERT | MOTHER<br>FATHER<br>OTHERS |

In addition, three composite scores can be computed, on the same basis, which assess physical, psychosocial and overall functioning. A copy of the SIP can be found in Appendix 6.

Psychometric properties of the SIP

There are many reports in the literature concerning the reliability and validity of this measure (Carter et al., 1976; Pollard et al., 1976; Bergner et al., 1976; Bergner et al., 1981). Work began on this questionnaire in 1972. The first version contained 312 items, based on statements derived from interviews with patients, carers, people without illness and health care professionals. Subsequent item analysis, on data obtained from 246 individuals (including patients and non-patients), resulted in a reduction from 312 to 189 items. The 189-item SIP was subjected to rigorous testing in trials conducted in 1974 and 1976, with particular attention being paid to the issues of reliability and validity. A conscious attempt was made to test as broad a range as possible of subjects with health-related dysfunction. Samples of subjects assessed have included: GP enrollees, rehabilitation out and in-patients, speech pathology inpatients, outpatients with chronic health problems, hyperthyroid patients, patients with rheumatoid arthritis and patients who had undergone hip replacements.

High test-retest stability coefficients have been noted in both trials. In the 1974 trial, 199 subjects completed the SIP questionnaire on 2 occasions with a test-retest interval of 24 hours. Two forms of the questionnaire: long version (235 items) vs short version (146 items) and 2 types of administration: interviewer and self-administered were compared. 6 interviewers were used. The test-retest reliability coefficients of category scores ranged between 0.75 and 0.92, dependent upon type of administration, different interviewers and severity of dysfunction of the patient group assessed. Reliability in terms of whether or not the same items were checked was lower (r=0.45-0.60). In the 1976 trial, 24-hour test retest reliability (n=53) for category and overall scores was high (r=0.92), however the reproducibility of items checked was lower (r=0.50).

Reliability was highest for self-administered, interviewer supervised mode of administration (r=0.97), with interviewer administration producing an lower reliability (r=0.87). No data were available regarding the test-retest reliability of questionnaires completed postally. However, the authors feel that postal questionnaires provide less reliable information as the correlations between the postally completed SIP scores and external criterion (for example, self assessment of dysfunction) were lower than for other types of administration. Internal consistency, as assessed by Cronbachs alpha, was also high (r=0.94).

The 1974 trial provided some evidence of the validity of the SIP in that it successfully discriminated between sub-groups of patients with varying degrees of dysfunction. In addition, SIP scores correlated with external criterion measures (patient and clinician subjective assessments of dysfunction). In 1976, a more detailed analysis of the convergent and discriminant validity of the SIP was performed utilising the multitrait-multimethod approach (Campbell and Fiske, 1959). In this analysis, 5 external criteria were assessed: 1) self assessment of dysfunction (SAD), 2) self assessment of sickness (SAS), 3) National Health Survey Index of Activity Limitation, Work Loss and Bed Days (NHIS), 4) clinician rating of dysfunction (CAD) and 5) clinician rating of sickness (CAS). Several hypotheses regarding the relationships between these variables were proposed and a hierarchy of correlations suggested: SIP and SAD > SIP and SAS > SIP and NHIS > SIP and CAD > SIP and CAS. This hierarchy was confirmed by the analysis providing some evidence of convergent and discriminant validity. In addition, the SIP category scores had a high mean test-retest correlation (r=0.82, SD=0.08) with a low mean correlation being seen between categories (r=0.32, SD=0.19 (Time 1); r=0.40, SD=0.21 (Time 2).

A further review of the content of the 189-item SIP resulted in the final 136-item version. The data from the 189-item version were re-scored (based on 136-items only) and re-analysed. The 136-item version performed as well or better than the longer version in terms of reliability and validity.

### 4.3.c.iii **Mood Adjective Checklist (MACL) (McNair and Lorr, 1964; Lishman, 1972)**

The Lishman version of the Mood Adjective Checklist (McNair and Lorr, 1964) was used to assess mood at time of testing. This 24 item checklist provides objective measures of anxiety, hostility, vigour, depression and fatigue. Patients are asked to rate how they feel on a 4-point scale, ranging from 'not at all' to 'extremely', on each of the 24 adjectives listed (see Appendix 7 for copy of this scale).

Psychometric properties of MACL

The version used in this study was of the same format as that used by Lishman (1972) in a study of the affective components of memory functioning. The study was conducted on psychiatric inpatients suffering from affective disorder. In this study, 3 measures of depression were employed: a clinical rating of depression; the Beck Depression Inventory and the depression sub-scale of the MACL. The author reports a high correlation between the MACL Depression score and the Beck Depression Inventory ($r=0.96$, $p<.05$) and a moderate correlation between the MACL Depression score and the clinical rating of depression ($r=0.64$, $p<05$), thus providing evidence of concurrent validity for this sub-scale. No other information regarding the other sub-scales of the MACL is given.

The version used was adapted from that described by McNair and Lorr (1964), originally containing 55 adjectives, covering five hypothesised moods: tension, anger, depression, vigour and fatigue. The factorial and concurrent validity of the mood factors and their sensitivity were determined by three main studies in which a total of 853 male psychiatric outpatients and 45 normal controls were assessed. In two of the studies the MACL was administered during treatment, while in the third the assessment was a one-off assessment. The form of the MACL varied across the three studies, reducing from 55 items in Study 1 to 38 items in Study 3.

The five factors proposed were confirmed by factor analysis of the items. In addition, two further factors relating to Confusion and Friendliness also emerged, though these were weaker factors. In addition, fatigue and vigour,

while negatively correlated do appear to be separate factors and not opposite poles of a bipolar factor. The five mood factors showed high congruence across the three studies, ie. the same factors were apparent in three separate studies, suggesting high validity of the proposed factors.

Evidence of test-retest reliability is reported from one study in which 150 male psychiatric outpatients were assessed prior to and following 4 weeks of treatment. The MACL administered in this study consisted of 38 adjectives covering 6 mood states: tension (8 items); anger (5 items); depression (9 items); vigour (6 items), fatigue (5 items) and confusion (5 items). Moderate correlation coefficients were seen for all scales (tension, r=0.64; anger, r=0.68; depression, r=0.69; vigour, r=0.64; fatigue, r=0.61; confusion, r=0.61).

Some evidence of the sensitivity of this measure is provided by one study (Study 3) in which 180 male psychiatric patients were compared to 45 normal controls. Significant differences were seen on all scales at the .001 level, with patients reporting higher levels of tension, anxiety, depression and fatigue and lower levels of vigour than controls. In the same study, in which patients were being treated with either drug therapy, psychotherapy or placebo, the MACL successfully detected drug/placebo differences in the experimental group, while the controls showed no evidence of mood change. This suggests that the questionnaire is sensitive to treatment effects. Work by Thompson and Trimble (1982b) in patients with epilepsy also demonstrates the sensitivity of the MACL in detecting drug-related changes. In comparison to a control group, who did not undergo any change to their antiepileptic medication, patients who were undergoing a drug reduction (from a mean of 2.8 drugs to a mean of 1.6 drugs) demonstrated a significant fall in anxiety as assessed by the MACL. This change in anxiety was also seen on another questionnaire, the Middlesex Hospital Questionnaire (MHQ) (Crown and Crisp, 1966). In addition, a group of patients whose therapy was changed by substituting carbamazepine therapy for one or more drugs, showed a significant reduction in anxiety and an increase in vigour. These changes, however, were not seen on the MHQ.

Scanty evidence regarding concurrent validity is given. Low, but significant correlations have been shown between MACL scales and independent measures of interpersonal behaviour (Interpersonal Behaviour Inventory, Lorr and McNair, 1963) and anxiety (Taylors's (1953) Manifest Anxiety scale) (McNair and Lorr, 1964).

The MACL appears to be minimally sensitive to social desirability of response set with 4 of the 5 scales showing low to moderate correlations with a scale of social desirability (tension, r=-.21; depression, r=-.36; vigour, r=.33; fatigue, r=-.18). However, the factor 'anger' did show a moderate correlation with social desirability (r=-.52).

In summary, data relating to the form of the MACL used in this study is scanty and chaotic, the reported reliability and sensitivity data arising from a number of studies with varying numbers of adjectives employed. No clear structure seems apparent for the testing of the psychometric properties of this test, the pervading feeling being that the analyses were performed ad hoc. Regarding test-retest reliability, it is difficult to equate this with a correlation between scores obtained on two separate occasions in which a change in treatment has occurred in the intervening interval.

4.3.c.iv **Life Events Schedule (LES) (Sarason et al., 1978)**
This questionnaire provides an objective measure of the occurrence and impact of significant life events. Patients check if any of the listed events (eg. new job, marriage) have occurred during the period of interest (6 months prior to study entry or since last visit for subsequent assessments). For any events defined, they are asked to rate on a 7-point scale, ranging from 'very positive' to 'very negative' what effect they feel that event has had on their lives. The version used in this project was an adaptation of the Life Events Schedule of Sarason et al. (1978). The main differences were: 1) the rating of the impact of the event is on a 5-point as opposed to a 7-point scale (as in the original version); 2) the number of events listed is reduced from 47 to 31 items. In the epilepsy version, items that it was felt were irrelevant to the population being studied were excluded (for example,

borrowing more that $10,000 (buying home, business, etc), foreclosure on mortgage). It was hypothesised that this reduction would not greatly alter the sensitivity of the questionnaire as three of the items are of an open format, that is, they allow the respondent to enter any events not already covered by the standard questionnaire. It was, thus, felt that if any important items had been excluded, there was an opportunity for the patient to include them. A copy of this scale can be found in Appendix 8.

Psychometric properties of LES

The limited work regarding the psychometric properties of this questionnaire has been conducted in psychology students (Sarason et al., 1978). Normative analyses in 345 students indicates that the LES is minimally influenced by sociodemographic variables, including gender. Two studies investigating test-retest reliability (with 34 and 58 subjects respectively) with an interval of 5-6 weeks indicates that this instrument has adequate reliability (r=.56-.88, negative and total score). Lower reliability coefficients were seen for the positive life events scores (r=.19-.53). The correlation between the LES scores (negative, positive and total) and a number of objective measures including anxiety, academic achievement, social desirability, personal maladjustment, depression, locus of control and the Schedule of Recent Experiences (Holmes and Rahe., 1967) were also investigated. No correlation with social desirability was seen. In general, the negative LES score correlated most highly with the dependent measures. The correlations were significant, though small, ranging from .20 (social nonconformity) to .46 (state anxiety). It seems that negative life events are a better predictor of life stress than positive life events. The total LES scores does not appear to provide additional information to the negative LES score, as evidenced by the finding that a balance score (negative events minus positive events) produced similar findings to the negative score alone. It thus seems that the mediating influence of positive life events on the effect of negative life events seems to be minimal.

#### 4.3.c.v Global Rating Scale

A question of interest to the current project was the relationship between the more detailed assessment (QOLAS) and patients' self assessment of their overall satisfaction. In order to address this issue, a global rating scale (GRS, copy in Appendix 9) was devised. This scale was developed to assess global satisfaction with the five general life domains covered by the QOLAS: physical ability, cognitive ability, emotional status, social functioning, economic status/employment status. The categories of economic and employment status were separated as patients often reported satisfaction with their employment or daytime activity but were not satisfied with their finances, and had difficulties in deciding on their overall satisfaction when both aspects were combined. In addition, patients were asked to assess their satisfaction with life in general. The resultant scale thus contains 7-items measuring satisfaction with life in general, physical, cognitive, emotional, social, economic and employment status. Patients rate their satisfaction with these areas on a 5-point scale, ranging from 'very satisfied' to 'very dissatisfied'.

#### 4.3.c.vi Construct Importance Scale

This questionnaire was devised to address two issues. First, are constructs important to the individuals quality of life elicited during the interview procedure?. That is, are we tapping what we think we are? The answer to this question is of relevance to the content validity of the test instrument. Secondly, the relationship between the patients actual functioning in key life domains and the importance attached by the individual to those domains/abilities has not been studied in any detail. Do QOL scores change if this variable (ie. importance) is taken into consideration and if so, how?
This questionnaire assesses the importance the patient places on each of the constructs elicited. A 5-point scale ranging from 'not important' to 'extremely important' is used. A copy of the questionnaire can be found in Appendix 10.

### 4.3.d Study design and procedure

The same study design and procedure were employed as in Study 1. Each assessment lasted approximately 1.5 hours.

## 4.4 STUDY 3: TRIGEMINAL NEURALGIA STUDY

### 4.4.a Aims

The aim of this study was to determine the sensitivity of the Quality of Life Assessment Schedule (QOLAS) in detecting changes in quality of life (QOL) following successful surgery for severe facial pain (trigeminal neuralgia).

### 4.4.b Subjects

Subjects were recruited from patients attending the Out-Patient Department of the National Hospital for Neurology and Neurosurgery, for pre-operative assessment of trigeminal neuralgia. Patients considering surgery were approached and the nature and purpose of the study was explained to them. Written, informed consent was obtained from all patients who participated in the study. Exclusion criteria included: patients with additional handicaps likely to influence their quality of life (for example, multiple sclerosis, physical disability, profound deafness) and which would not be affected by surgery; patients unable or unwilling to take part in the study.

### 4.4.c Measures

All patients completed the same questionnaires as in Study 2, namely:

1. Quality of Life Assessment Schedule (QOLAS)
2. Sickness Impact Profile
3. Mood Adjective Checklist
4. Life Events Schedule
5. Global Rating Scale
6. Construct Importance Scale

In addition, the trigeminal neuralgia group completed the following questionnaires:

4.4.c.i **McGill Pain Questionnaire (Melzack, 1975)**

This questionnaire was designed to provide quantitative measures of clinical pain. Patients are asked to rate their present pain on a 1-5 intensity scale and to select words which best describe their pain from a list of 78 descriptors. The three outcome measures are: 1) pain rating index (PRI) based on the rating of present pain (1-5 intensity scale), 2) number of words chosen (NWC) and 3) present pain intensity (PPI), based on a severity scale determined for each word. A copy of this questionnaire can be found in Appendix 11.

4.4.c.ii **Hospital Anxiety and Depression Scale (Zigmond and Snaith, 1983)**

This brief, 16-item, self-assessment scales measures anxiety and depression. It excludes items related to physical illness (such as dizziness, headaches etc.) thus countering criticisms that many mood questionnaire scores are affected by the physical illness of the patient. For both sub-scales, a score less than 7 indicates no evidence of psychopathology, a score between 8 and 10 indicates a doubtful 'case' and a score greater than 11 indicates the presence of psychopathology. A copy of this questionnaire can be found in Appendix 12.

4.4.d **Study design**

The study was of a prospective, follow-up design. Patients were assessed pre-operatively and again 5 weeks after operation.

4.4.e **Procedure**

Patients were interviewed during their pre-operative assessment to determine the constructs (areas of importance to quality of life) which would form the basis of their individual Quality of Life Assessment Schedule (QOLAS). A revised version of the semi-structured interview used in the epilepsy group was used (see Appendix 13 for copy). Questionnaires were then completed by postal contact on both occasions.

# CHAPTER 5
# ANALYSES

## 5.1 DATA MANIPULATIONS

### 5.1.a Standardisation of repertory grid data

During the course of the project a number of changes to the technique were made. These included changes in the elements employed, an increase in the number of constructs elicited and changes in the rating method used (See Table 4.5, Chapter 4 for summary of these alterations). In order to maximise the amount of data available, "standardised" grid data were analysed. These standardised grids comprised of the first 10 constructs elicited for each patient and the 7 elements: NOW, BEFORE, LIKE, EXPECT, FRIEND, BEST, WORST. These factors were common to all patients and remained unchanged throughout all studies. In addition, all ratings were recoded to the 1-5 Likert format where 1=No problem, 2=A slight problem, 3=A moderate problem, 4=A big problem and 5=It could not be worse. Recoding was carried out as follows:

| | |
|---|---|
| 100 mm visual analogue scale: | 81-100 = 1 |
| | 60-80 = 2 |
| | 40-59 = 3 |
| | 20-39 = 4 |
| | 0-19 = 5 |
| 10-point, dashed Likert scale | 1-2 = 1 |
| | 3-4 = 2 |
| | 5-6 = 3 |
| | 7-8 = 4 |
| | 9-10= 5 |

There was a reversal in coding between the 100mm VAS and the 10-point Likert scale. In the 100mm VAS rating the measure used was distance from 'Severe problem' end so that a score of 0 indicated 'No problem' and a score of 100 'A severe problem'. This was reversed for the 10-item VAS rating so that a score of 1 indicated 'No problem' and a score of 10 'A severe problem', thus the higher the score, the greater the degree of difficulty or problem.

### 5.1.b Scoring of repertory grids: deriving appropriate RG-based measures of QOL

An attempt has been made to define both aggregate and profile measures of quality of life. All these are based on inter-element distances. The theoretical basis of the technique has been described in detail previously. To recap briefly, quality

of life is viewed as a concept in which future expectations or aspirations have a role to play. It is thus proposed that the distance between the elements 'as you are NOW' and 'as you would LIKE to be' is an important measure as it relates to the discrepancy between current situation (as you are now) and aspirations (how you would like to be). This is termed the NOW-LIKE distance. In addition, QOL is seen as a comparative phenomena in which the position of an individual in relation to their peers and their past abilities are important factors in the determination of their QOL.

5.1.b.i **Aggregate measures of QOL: Single indices**

On a theoretical basis, 5 possible aggregate measures were proposed and subjected to empirical testing (ABS, DIR, ABS6, DIR6, ABS21). These are described in detail below, together with worked examples based on hypothetical grid data (see Figure 5.1).

ABS: the absolute NOW-LIKE distance. This is the absolute distance between the elements 'as you are now' and 'as you would like to be', summed over all ten constructs.

Worked example:

```
ABS  =   abs(5-1)+abs(4-1)+abs(2-1)+abs(3-
         1)+abs(1-3)+abs(2-1)+abs(3-1)+abs(3-
         1)+abs(1-3)+abs(5-1).
     =   (4)+(3)+(1)+(2)+(2)+(1)+(2)+(2)+(2)+(4).
     =   23.
```

DIR: the directional NOW-LIKE distance. This is calculated in exactly the same way as ABS, but taking the direction of the NOW-LIKE discrepancy into consideration.

Worked example:

```
DIR  =   (5-1)+(4-1)+(2-1)+(3-1)+(1-3)+(2-1)+(3-
         1)+(3-1)+(1-3)+(5-1).
     =   (4)+(3)+(1)+(2)+(-2)+(1)+(2)+(2)+
         (-2)+(4).
     =   15
```

Figure 5.1: Example of completed, standardised (10*7) repertory grid.

| | ELEMENTS | | | | | | |
|---|---|---|---|---|---|---|---|
| | Now | Before | Like | Expect | Friend | Best life | Worst life |
| Construct 1 | 5 | 1 | 1 | 2 | 1 | 1 | 5 |
| Construct 2 | 4 | 2 | 1 | 3 | 1 | 2 | 5 |
| Construct 3 | 2 | 2 | 1 | 2 | 3 | 2 | 5 |
| Construct 4 | 3 | 1 | 1 | 2 | 1 | 2 | 5 |
| Construct 5 | 1 | 1 | 3 | 3 | 4 | 1 | 5 |
| Construct 6 | 2 | 1 | 1 | 2 | 4 | 1 | 5 |
| Construct 7 | 3 | 2 | 1 | 2 | 2 | 1 | 5 |
| Construct 8 | 3 | 3 | 1 | 2 | 3 | 2 | 5 |
| Construct 9 | 1 | 1 | 3 | 2 | 1 | 2 | 5 |
| Construct 10 | 5 | 3 | 1 | 3 | 2 | 2 | 5 |

Key: 1=No problem, 2=A slight problem, 3=A moderate problem, 4=A big problem, 5=It could not be worse.

ABS6: this score takes the relative nature of QOL into account by comparing how far the individual is from his ideal (the NOW-LIKE distance) with how far away he sees other periods of his life and other people from this ideal (all other element-LIKE distances. It is calculated by ranking the absolute NOW-LIKE distance against all other element to LIKE distances (BEFORE-LIKE, EXPECT-LIKE, FRIEND-LIKE, BEST LIFE-LIKE, WORST LIFE-LIKE). As in calculating ABS, the absolute distances are calculated and summed over all constructs. Ranking is performed such that the smallest discrepancy is given a rank of 1 and the largest a rank of 6. This is based on the assumption that the closer an element is rated to the ideal LIKE (as you would like to be), the more satisfactory the QOL of that rated element is seen by the individual performing the rating.

Worked example:

| | Absolute discrepancies | | | | | |
|---|---|---|---|---|---|---|
| | N-L | B-L | E-L | F-L | BE-L | W-L |
| Construct 1 | 4 | 0 | 1 | 0 | 0 | 4 |
| Construct 2 | 3 | 1 | 2 | 0 | 1 | 4 |
| Construct 3 | 1 | 1 | 1 | 2 | 1 | 4 |
| Construct 4 | 2 | 0 | 1 | 0 | 1 | 4 |
| Construct 5 | 2 | 2 | 0 | 1 | 2 | 2 |
| Construct 6 | 1 | 0 | 1 | 3 | 0 | 4 |
| Construct 7 | 2 | 1 | 1 | 1 | 0 | 4 |
| Construct 8 | 2 | 2 | 1 | 2 | 1 | 4 |
| Construct 9 | 2 | 2 | 1 | 2 | 1 | 2 |
| Construct 10 | 4 | 2 | 2 | 1 | 1 | 4 |
| TOTALS | 23 | 11 | 11 | 12 | 8 | 36 |
| RANK | 5 | 2.5 | 2.5 | 4 | 1 | 6 |

**ABS6 score=5.**

Key: N-L = (Now-Like) distance
B-L = (Before-Like) distance
E-L = (Expect-Like) distance
F-L = (Friend-Like) distance
BE-L= (Best life-Like) distance
W-L = (Worst life-Like) distance

DIR6: this is calculated in exactly the same way as ABS6, however, the direction of the element-Like distances are taken into account.

Worked example:

| | Directional discrepancies | | | | | |
|---|---|---|---|---|---|---|
| | N-L | B-L | E-L | F-L | BE-L | W-L |
| Construct 1 | 4 | 0 | 1 | 0 | 0 | 4 |
| Construct 2 | 3 | 1 | 2 | 0 | 1 | 4 |
| Construct 3 | 1 | 1 | 1 | 2 | 1 | 4 |
| Construct 4 | 2 | 0 | 1 | 0 | 1 | 4 |
| Construct 5 | -2 | -2 | 0 | 1 | -2 | 2 |
| Construct 6 | 1 | 0 | 1 | 3 | 0 | 4 |
| Construct 7 | 2 | 1 | 1 | 1 | 0 | 4 |
| Construct 8 | 2 | 2 | 1 | 2 | 1 | 4 |
| Construct 9 | -2 | -2 | -1 | -2 | -1 | 2 |
| Construct 10 | 4 | 2 | 2 | 1 | 1 | 4 |
| TOTALS | 15 | 3 | 9 | 8 | 2 | 36 |
| RANK | 5 | 2 | 4 | 3 | 1 | 6 |

**DIR6 score=5.**

Key: as for worked example of ABS6.

ABS21: this is the absolute NOW-LIKE distance ranked against all other possible element-element distances (7 elements produce 21 possible inter-element distances). The principles for calculating distances and performing ranking are identical to those used when calculating ABS6. This measure is, however, complex and tedious to calculate by hand and thus a worked example is not given. A specifically developed SAS program (SAS, 1985) was employed to calculate all ABS21 scores.

5.1.b.ii **Profile grid measures**

Two methods were used to calculate profile scores and these are described below:

Calculation of profile scores: Method 1

Constructs were classified into five categories (physical, cognitive, emotional, social and economic/employment) by three raters (including the main experimenter, AM) on two occasions at an interval of approximately 1 week. A score of 0 indicated that the construct did not belong in a category and a score of 1 that it did (see Figure 5.2 for example of rating).

Figure 5.2: Classification of constructs

| | Categories | | | | |
|---|---|---|---|---|---|
| Constructs | P | C | E | S | W |
| Fits | 1 | 0 | 0 | 0 | 0 |
| Aggression | 0 | 0 | 1 | 0 | 0 |
| Making friends | 0 | 0 | 0 | 1 | 0 |
| Social life | 0 | 0 | 1 | 1 | 0 |
| Anxiety | 0 | 0 | 1 | 0 | 0 |
| Being a caring person | 0 | 0 | 1 | 1 | 0 |

P=Physical; C=Cognitive; E=Emotional; S=Social;
W=Economic/employment.

Multiple allocations were permitted. This enabled data on within- and between-rater reliability to be collected. Scores for each of the 5 areas of life functioning considered to be of importance to QOL were calculated, namely: physical functioning (PHYS1), cognitive abilities (COG1), emotional status (EMOT1), social functioning (SOC1) and economic/employment status (WORK1).

A weighting for each construct for all 5 areas (PHYS, COG, EMOT, SOC, WORK) was calculated by summing the ratings (0 or 1) given by each rater on each occasion. This resulted in a weight with a possible range of 0 to 6, with a score of 0 indicating that no rater on either occasion had placed the construct in that category and a score of 6 when all three raters on both occasions had placed the construct in that category.

Worked example:

| | Construct 'fits' | | | | | Construct 'being in work' | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| | P | C | E | S | W | P | C | E | S | W |
| Rater 1, occasion 1 | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 1 |
| Rater 2, occasion 1 | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 1 |
| Rater 3, occasion 1 | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 |
| Rater 1, occasion 2 | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 |
| Rater 2, occasion 2 | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 |
| Rater 3, occasion 2 | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 |

In this example, the construct 'Fits' has a weighting of 6 for the PHYSICAL category and 0 for all other categories (COG, EMOT, SOC, WORK). Similarly, the construct 'Being in work' would have a weighting of 6 for the WORK category, a weighting of 2 for the SOCIAL category and 0 for all other categories.

Profile scores for each category were then calculated by multiplying the absolute NOW-LIKE distance for each construct by the weighting given for that construct in each category (PHYS, COG, EMOT, SOC, WORK) and summing over all constructs with a weighting in that category. In the worked example given below, a weighting in the PHYSICAL category is given to the constructs 'fits', 'fatigue', 'aggression' and 'being in work' of 6,6,2 and 1 respectively. Multipying these weightings by the NOW-LIKE distance for each of these constructs and summing over the 4 constructs gives a total PHYSICAL domain score of 40.

Worked example:

| Construct: | Abs (N-L) distance | Category weightings PHYS | COG | EMOT | SOC | WORK |
|---|---|---|---|---|---|---|
| Fits | 3 | 6 | 0 | 0 | 0 | 0 |
| Fatigue | 2 | 6 | 0 | 0 | 0 | 0 |
| Memory | 4 | 0 | 6 | 0 | 0 | 0 |
| Concentration | 4 | 0 | 6 | 0 | 0 | 1 |
| Aggression | 3 | 2 | 0 | 6 | 0 | 0 |
| Anxiety | 2 | 0 | 0 | 6 | 0 | 0 |
| Making friends | 4 | 0 | 0 | 2 | 6 | 0 |
| Social life | 2 | 0 | 0 | 0 | 6 | 0 |
| Being in work | 4 | 1 | 0 | 1 | 0 | 6 |
| Finances | 2 | 0 | 0 | 0 | 3 | 6 |

Profile scores=Abs(N-L) distance * category weighting

PHYS1 = (3*6)+(2*6)+(3*2)+(4*1)=40.
COG1 = (4*6)+(4*6)=48.
EMOT1 = (3*6)+(2*6)+(4*2)+(4*1)=42.
SOC1 = (4*6)+(4*6)+(2*3)=54.
WORK1 = (4*1)+(4*6)+(2*6)=40.

Calculation of profile scores: Method 2

This method was introduced in an attempt to simplify the procedure for calculating profile scores. Method 1 has obvious advantages in that it is possible to validate the assignment of constructs into categories. However, for practical application it is lengthy and cumbersome and likely to limit the usefulness of the scoring method. Differences between methods 1 and 2 in terms of test-retest reliability, sensitivity and validity will be of interest in determining the value of these scoring methods for practical application.

Constructs were designated to a single category (PHYS or COG or EMOT or SOC or WORK) based upon the judgement of the experimenter (alternatively classification could be obtained from the patient during interview). Profile scores were calculated as the sum of the absolute NOW-LIKE distance for the constructs placed within a category. A worked example is given below.

Worked example:

| | Now | Like | Abs(Now-Like) distance |
|---|---|---|---|
| Physical | | | |
| Fits | 5 | 1 | 4 |
| Fatigue | 3 | 2 | 1 |
| Cognitive | | | |
| Memory | 2 | 1 | 1 |
| Concentration | 4 | 2 | 2 |

Profile scores: PHYS2 = 4+1 = 5
COG2 = 1+2 = 3.

## 5.2 STATISTICAL PROCEDURES

All data were analysed using the microcomputer version of the Statistical Package for the Social Sciences (SPSS PC+) (Norusis, 1983). Repertory grids were analysed using programs developed on SAS (SAS, 1985) by an independent programmer.

### 5.2.a Simple data description

The normality of the distributions of all variables (demographic, repertory grid and questionnaire data) were investigated by viewing histogram plots and, more formally, through the Kolmogorov-Smirnov test for normality (Norusis, 1983).

The populations studied were defined using frequencies analysis of all demographic variables. Differences between patients entered into Studies 1 and 2 were tested using either 1-way analysis of variance techniques (Norusis, 1983) or the non-parametric equivalent (Wilcoxon-Mann Whitney U statistic) (Siegel and Castellan, 1988), dependent upon the normality of the variable distribution.

### 5.2.b Psychometric properties of all measures

#### 5.2.b.i Influence of age and IQ

The influence of age and intellectual level (full-scale IQ, performance IQ and verbal IQ) on the RG-based aggregate quality of life measures (ABS, DIR, ABS6, DIR6, ABS21) were investigated by calculating Pearson product moment correlation coefficients (Norusis, 1983). Listwise deletion was used and 2-tailed probabilities are reported. These correlations were performed on all subjects with RG data available at baseline

(n=50). Due to uncertainty regarding the normality of the distributions of ABS6 and DIR6 (they show normal distributions on some occasions but not others) Spearmans rank order correlation coefficients (Siegel and Castellan, 1988) were calculated in addition for these variables. The findings were similar to the parametric analyses. Parametric findings are quoted in the results for all five global QOL measures.
Identical parametric analyses were performed on RG-profile measures (PHYS1, COG1, EMOT1, SOC1, WORK1, PHYS2, COG2, EMOT2, SOC2, WORK2).

To assess the influence of age and IQ on the additional questionnaires employed (SIP, MACL, LES, GRS, CIS), Pearson product moment correlation coefficients (MACL, GRS) or Spearman rank-order correlation coefficients were calculated (SIP, LES, CIS) for all patients (Study 1 and 2) for whom data was available on occasion 4 (See Table 5.3 for details of group numbers for the individual questionnaires). Session 4 was chosen in order to maximise the number of patients with available questionnaire data, thus enhancing the power of the statistical analyses. For a 2-tailed test, a significance level of .01 and an N of 41, the study has a 80% power of detecting a significant correlation of 0.5 or greater (Machin and Campbell, 1987).

5.2.b.ii **Gender effects**

Gender differences in relation to RG-based QOL scores were assessed initially through one-way analysis of variance or Mann-Whitney U statistic (SIP, LES, CIS) on all patients with RG data available at baseline (n=50). Due to the small number of females in the study (n=9) a further analysis in which the nine females were matched on IQ, age and seizure type to nine males was carried out. A one-way analysis of variance on this sub-group of patients provided further evidence of the influence of gender on QOL scores (aggregate and profile). Similar analyses were performed for all other questionnaire scores (SIP, LES, MACL, GRS, CIS) using data from Session 4. Mann-Whitney U tests were used for a number of SIP sub-scales (BCM, SI, REC, HM, WORK and EAT) and the MACL Hostility scale, due to non-normality of these data.

Table 5.3: Numbers of epilepsy cases with valid questionnaire data.

| Measure | S1 | S2 | S3 | S4 |
|---|---|---|---|---|
| RG | 50 | 49 | 47 | 44 |
| GRS | 25 | 25 | 24 | 25 |
| CIS | 20 | 20 | 18 | 19 |
| SIP | 26 | 23 | 37 | 39 |
| MACL | 26 | 28 | 37 | 43 |
| LES | 26 | 28 | 37 | 44 |

S1, Baseline; S2, 1 month; S3, 3 months; S4, 6 months.
RG, repertory grid; GRS, global rating scale; SIP, Sickness Impact Profile; MACL, Mood Adjective Checklist; LES, Life Events Schedule

5.2.b.iii **Temporal stability**

The temporal stability of the proposed aggregate measures of QOL (ABS, DIR, ABS6, DIR6, ABS21) were evaluated using Pearson product moment correlations, calculated across all session pairings (S1vS2; S1vS3; S1vS4; S2vS3; S2vS4; S3vS4) for epilepsy patients with complete RG data on all 4 occasions (n=43). This provided information regarding stability across differing time periods, ranging from one to six months. All correlational analyses employed listwise deletion, with 2-tailed probabilities being reported. Thus, only patients with data on all 4 occasions were included in the analyses of temporal stability. This enabled direct comparisons of the various time periods to be made. Similar analyses were conducted on the RG profile scores (PHYS, COG, EMOT, SOC, WORK; methods 1 and 2).

Study 2 data were used to evaluate the temporal stability of the Sickness Impact Profile (SIP), the Mood Adjective Checklist (MACL), the Life Events Scale (LES) and the Global Rating Scale (GRS). Pearson correlation coefficients are quoted for the MACL and GRS, however, due to non-normality of the data, Spearman rho coefficients were used for SIP and LES data. Only patients with data available on all 4 occasions for any given questionnaire were used in the analysis.

5.2.b.iv **Sensitivity**

Three types of analysis were performed to investigate the sensitivity of the RG-based QOL measures (both aggregate and profile). The first analysis involved patients entered into Study 1 (epilepsy patients) who had complete data on all 4 occasions (n=19). These were divided into two groups according to whether or not they had reported any significant life events during the course of the study. It was hypothesised that those patients experiencing significant life events would show greater change in their QOL scores than those not experiencing any major life events. The absolute change in QOL scores between S1 (Baseline) and S4 (6 months) were calculated and a one-way analysis of variance was used to investigate the discriminant power of all the proposed QOL measures (aggregate and profile).

The second analysis involved a group of 24 epilepsy patients Study 2) in whom correlational analyses were performed between the absolute change in aggregate QOL measures for all session pairings (1v2, 1v3, 1v4, 2v3, 2v4, 3v4) and scores obtained on the LES for the same time periods. The LES asks about the occurrence of life events since previous visit, thus replies on session 2 to the LES would be expected to correlate with the change in QOL scores from session 1 to session 2. Similarly, LES scores obtained at session 3 would relate to any changes occurring between sessions 2 and 3 and thus would be expected to be correlated with the change in QOL scores from session 2 to session 3. Intervals not covered directly by LES raw scores were computed by adding LES data for adjacent periods (see Table 5.4 for summary). Correlations were performed separately for negative life events, positive life events and a life events discrepancy score (calculated as positive events minus negative events). Due to the non-normality of the LES data, Spearman rank order correlation coefficients were computed throughout. Only patients with valid RG and LES data on all 4 occasions were included in the analysis. Identical analyses were conducted to assess the sensitivity of the profile RG measures, SIP, MACL and GRS.

The third analysis was conducted in the trigeminal neuralgia group (Study 3) who were used to determine the sensitivity of the RG-based QOL measures and to compare this with the ability of the independent measures (MACL, SIP, GRS) to detect changes in mood and QOL. Student paired t-test were employed, comparing pre- and post-operative scores for all measures (RG, SIP, MACL, GRS).

5.2.b.v **Validity:**

Baseline scores for Study 2 patients (n=25) were analysed to investigate the validity of the RG-based QOL measures and the independent questionnaires employed in the study. A multi-trait, multi-method approach was taken (Campbell and Fiske, 1959). This approach proposes that higher correlations will be seen between measures addressing the same underlying trait (single trait, multi-method correlations) than between

Table 5.4: Summary of derived LES scores

| Interval | Score employed |
|---|---|
| S1 - S2 | LES score (S2) |
| S1 - S3 | LES score (S2) + LES score (S3) |
| S1 - S4 | LES score (S2) + LES score (S3) + LES score (S4) |
| S2 - S3 | LES score (S3) |
| S2 - S4 | LES score (S3) + LES score (S4) |
| S3 - S4 | LES score (S4) |
| Discrepancy score | = Absolute value (LES positive score - LES negative score) |

Key: S1=Session 1; S2=Session 2; S3=Session 3; S4=Session 4.

measures assessing different traits (multi-trait, multi-method correlations). Single trait, multi-method correlations provide evidence regarding convergent validity, while multi-trait, multi-method correlations concern divergent validity. Within method correlations (multi-trait, single method) are expected to hold an intermediate position, giving useful information regarding possible method artefacts. Pearson product moment correlation coefficients were used throughout these analyses.

The multi-trait, multi-method matrix tested is outlined in Table 5.5. The matrix is structured so as to include the 5 key areas important to assessment of QOL, namely, physical functioning, cognitive abilities, emotional status, social functioning and economic/employment status. From this postulated matrix it is possible to obtain information concerning the validity of the RG-based QOL measures (aggregate and profile) and also some limited data relating to the validity of the independent measures used in this study.

Within-method correlations for each measure (aggregate and profile QOL scores, SIP, MACL, and GRS) were calculated to assess the strength of multi-trait, single method associations. Spearmans rank order correlations are reported for the SIP (due to uncertainty regarding the normality of a number of the SIP sub-scales); Pearson product moment correlation coefficients were employed for all other measures. To enable direct comparisons of the strength of correlations between these analyses and those of the multi-trait, multi-method matrix outlined above, the same group of patients were used in both analyses.

## 5.3 GENERAL PROPERTIES OF REPERTORY GRIDS

### 5.3.a Effect of standardising ranking method

Prior to performing formal analyses of the RG measures (aggregate and profile), the effect of standardising the grids through recoding of the response formats was investigated. The changes in rating methods were made as a result of practical difficulties (time taken to complete questionnaire, lack of understanding of rating method). In addition, it was noted that patients did not appear to be using the 100mm VAS and 10-

Table 5.5: Proposed multi-trait, multi-method matrix, including expected inter-measure correlations within five key domains (PCASE)

| DOMAIN | MEASURES | |
|---|---|---|
| Physical functioning | RG | Physical profile score (PHYS1, PHYS2) |
| | GRS | Physical ability (Q2) |
| | SIP | Physical disability score |
| Cognitive functioning | RG | Cognitive profile score (COG1, COG2) |
| | GRS | Cognitive ability (Q3) |
| | SIP | Alertness behaviour, Psychosocial score |
| Emotional status | RG | Emotional profile score (EMOT1, EMOT2) |
| | GRS | Emotions (Q4) |
| | MACL | Anxiety, Fatigue, Hostility, Vigour, Depression |
| | SIP | Emotional behaviour, Psychosocial score |
| Social functioning | RG | Social profile score (SOC1, SOC2) |
| | SIP | Social interaction, Communication, Psychosocial disability score |
| | GRS | Social life (Q5) |
| Economic/Employment | RG | Economic/employment score (WORK1, WORK2) |
| | GRS | Employment (GRS6), Finances (GRS7) |
| | SIP | Work dimension score |
| Global evaluations | RG | ABS, DIR, ABS6, DIR6, ABS21 |
| | GRS | Satisfaction with life in general(GRS1) |
| | SIP | Total disability score |

RG, repertory grid measures; GRS, global rating scale; SIP, Sickness Impact Profile; MACL, Mood Adjective Checklist.

item Likert type scales fully, tending to use the extreme ratings. As the rating scales had been revised in order to simplify the procedure and increase patient understanding, it was hypothesised post-hoc that simplification of the rating procedure (from a 100mm VAS to a 10-point dashed Likert type scale to a 1-5 labelled Likert scale) would result in a greater distribution of scores across the 5 categories. Differences between the rating methods regarding the use of extremity scores were investigated by calculating (from the recoded 1-5 ratings) the absolute deviation from the central score (3). Thus the deviation score for an individual rating is 0, 1 or 2 and the total summed across all 70 ratings in the standardised grid has a range of between 0 and 140. A high deviation score indicates more use of extreme ratings. Means and 95% confidence intervals (CI) (Gardner and Altman, 1989) of the deviation scores were calculated and compared for the three ratings groups (0-100 VAS, 1-10 Likert, 1-5 Likert). Differences between these groups were further investigated by a 2-way analysis of variance (Norusis, 1988) with rating method as on independent variable and occasion as the other (repeated) independent effect.

5.3.b **Construct and element stability**

The following analyses were performed on 43 patients with epilepsy, for whom data was available on all 4 occasions:

a. The total variance across 4 sessions for each data point on the repertory grid (ie. each construct*element rating) was calculated for each patient. The standardised 10 construct by 7 element grids were used, thus 70 variances per patient were computed. The variance across sessions is calculated as:

$$Var=\Sigma_i^n \ (x_i - mean)^2/n-1$$

where i=rating (range 1 to 5) and n=number of sessions. The maximum possible variation between ratings over 4 occasions is thus:

| | Session | | | |
|---|---|---|---|---|
| | 1 | 2 | 3 | 4 |
| i= | 1 | 5 | 5 | 1 |
| or | 5 | 1 | 5 | 1 |
| or | 5 | 5 | 1 | 1 |
| or | 1 | 1 | 5 | 5 |
| or | 1 | 5 | 5 | 1 |
| or | 5 | 1 | 1 | 5 |

Mean=3 and variance=$\Sigma_i^n$ $(x_i - \text{mean})^2/n-1$, therefore maximum possible variance across 4 sessions= 16/3=5.33.

b. Variances were summed across all 7 elements to calculate the total variances for the individual constructs (Construct 1 ..... Construct 10) (CONVAR). The maximum possible variance for any one construct (summed over the 7 elements) is 16/3*7=37.3.

c. Variances were summed across all 10 constructs to calculate the total variances for each element (NOW, BEFORE, LIKE, EXPECT, FRIEND, BEST LIFE, WORST LIFE) (ELVAR). The maximum possible variance for an individual element (summed over all 10 constructs) is 16/3*10=53.3.

d. In addition, variances were summed over all 10 constructs and 7 elements to provide a total grid variance score (TOTVAR). This was used as a check as the sum of the variances of the 7 elements plus the sum of the variance of the 10 constructs should equal the total grid variance. The maximum total grid variance (based on 70 points) is 16/3*70=371.

e. Individual patient data and mean variances for elements and constructs were listed and examined to evaluate between-subject variability.

f. Kendall's coefficient of concordance (W) was calculated for construct and element variances to investigate the rank order of variability over occasions. Is there an ordering of elements in terms of variability? Is there an ordering of constructs? It is hypothesised that some ordering of the elements is likely, particularly as the elements used were stable across patients (i.e. all patients completed the same elements: NOW, BEFORE, LIKE, EXPECT, FRIEND, BEST LIFE, WORST LIFE). It was expected that little variation would be seen for the elements BEFORE, FRIEND, BEST LIFE and WORST LIFE as these are

fairly concrete situations. NOW and EXPECT might be expected to show some degree of variability. People's situations change as do their expectations. It is, therefore, also possible that the element LIKE (a measure of people's aspirations may also change over time. No such ordering is expected for constructs as the constructs used in the RG varied across patients.

## 5.4 INFLUENCE OF EPILEPSY VARIABLES

Baseline data were evaluated to assess the influence of epilepsy variables on the RG measures (aggregate, profile method 1 and profile method 2). Due to questionable normality, non-parametric analyses were used throughout. The influence of categorical variables (aetiology, history of status, family history, EEG focus, number of seizure types, seizure type and monotherapy/polytherapy) were investigated by either the Mann-Whitney U test (for 2 group variables) or the Kruskal-Wallis one-way analysis of variance test. Spearman correlation coefficients were calculated to assess the impact of continuous epilepsy variables (age of onset, duration of epilepsy, seizure rate and medication dosage) on RG data.

## 5.5 ANALYSIS OF CONSTRUCT IMPORTANCE SCALE (CIS)

18 patients completed the CIS on all 4 occasions. Analysis of the effects of age, IQ and gender on this scale have been described previously (this chapter).

Temporal stability was evaluated by 2 types of analysis. First, Spearman correlations were calculated across all session pairings for combined means scores (CISTOT1 to CISTOT4, all constructs combined) and; second, Spearman correlations for individual construct importance ratings (CIS1 to CIS15).

The existence of response bias in the CIS data was investigated by an analysis of variance of CIS ratings by individual patients. This was done to evaluate between-subject variability in their use of the CIS rating scale (range from 1=not important to 5=extremely important). In addition the

association between CIS ratings and the RG mean deviation score (described previously, this chapter) was investigated using Spearmans rank order correlation.

# CHAPTER 6

# RESULTS

## 6.1 PATIENT DETAILS

## 6.1 PATIENT DETAILS

### 6.1.a All epilepsy patients (Studies 1 and 2 combined)

64 patients in total were interviewed for inclusion in the study. 14 of these were excluded after session 1; 11/14 due to an inability to understand the repertory grid technique and 3/14 because of illness. Of the remaining 50 patients, a further 7 patients had incomplete data. 4 of these missed 1 or 2 appointments (1 missed session 3 only, 1 missed sessions 2 and 4, and 2 missed sessions 3 and 4), 1 patient refused to complete his 6 month assessment, and 2 patients moved away from the area and were uncontactable. In total, 50 patients completed session 1, 49 completed session 2, 47 completed session 3 and 44 completed session 4. The demographic, epilepsy and medication details for all patients with data on at least 2 occasions are given in Appendices 14 to 16.

The final group consisted of 43 patients for whom data was available on all 4 occasions. The mean age of the final group was 44.37 years (range 20-68, SD=12.2) with a mean FSIQ of 88.62 (range 67-108, SD=10.7). 36 were male and 9/43 were left handed. With regard to their social situation, 41/43 were single, 1 patient was married and 1 was divorced. 37 were long term residents at the Chalfont Centre for Epilepsy and 6 lived in an independent hostel, close to the centre, but administered by a separate organisation. The majority of the group (34/43) were in sheltered employment, 4 were retired, 3 were unemployed, 1 was in part-time open employment and 1 was engaged in voluntary work. 20 patients had never been in open employment. Of those who had experience of open employment, the mean duration of work was 9.8 years (range 1-35, SD=10.4). This finding is in keeping with the educational level of the group, as although many had been educated in main stream schools (31/43), only 12 had attained any qualifications (CSE's, 'O' levels or vocational). None of the group had gone on to higher education.

#### 6.1.a.i Details of epilepsy

The group as a whole had a long history of epilepsy with an early age of onset. The mean duration of the epilepsy was 35.2

years (range 12-59, SD=11.5), with a mean age of onset of 9 years (range 1-32, SD=6.3). The majority of patients (33/43) had complex partial seizures with or without secondary generalisation, 2 patients experienced simple partial seizures, 5 had primary generalised seizures and 3 had seizure types which were considered unclassifiable. 11 patients had 1 seizure type alone, 30 had 2 seizure types and 2 patients had 3 types of seizure (see Table 6.1).

Inter-ictal EEG records were available for all patients. 2 had normal EEG records, 24 had focal activity on the EEG and 17 were classified as having generalised activity.

With regard to medication, 19 patients were taking phenytoin (mean dose=367 mg/day, range 275-500), 27 were taking carbamazepine (mean dose=1259 mg/day, range 800-1800), 13 were taking sodium valproate (mean dose=1884, range 1000-3000), 13 patients were taking primidone (mean dose=676 mg/day, range=50-1250) and 12 were on clobazam (mean dose=12mg/day, range=5-30). In addition, 2 patients were taking phenobarbitone (daily doses of 120mg and 150 mg respectively) and 1 patient was on ethosuximide (daily dose=-500mg). The majority of patients were prescribed polytherapy (32/43). Full medication details are given in Table 6.2.

6.1.b **Comparison of patients entered into Studies 1 and 2**

Patients entered into Study 1 and Study 2 were similar on the majority of demographic and epilepsy variables including age, sex, intellectual level, age of onset and duration of epilepsy, aetiology, seizure type, EEG classification and medication prescribed. There was, however, a significantly higher incidence of patients with neurological deficits in Study 2 as compared to Study 1 (Chi-square=5.45, $p<.02$). Study 1 contained a number of patients who were resident at an independent hostel close to the centre and thus had a larger number of patients who had experience of open employment (Study 1, n=16/24; Study 2, n=9/26). This difference was significant at the .05 level (Chi-square=3.93, $p<.048$). Of those patients with experience of open employment, however, there were no apparent differences with regard to number of years in employment.

Table 6.1: Epilepsy details: patients with complete data only (all 4 occasions).

| Variable | Statistic | All patients N=43 | Study 1 N=19 | Study 2 N=24 |
|---|---|---|---|---|
| Age of onset (yrs) | Mean (SD) | 9.0 (6.3) | 10.7 (5.6) | 7.7 (6.7) |
| | Median (Range | 8.5 (1-32) | 11.0 (1-20) | 7.0 (1-32) |
| Duration (yrs) | Mean (SD) | 35.2 (11.5) | 35.5 (11.2) | 35 (12) |
| | Median (Range) | 33.5 (12-59) | 36 (12-54) | 32 (13-59) |
| Aetiology | Known | 42% | 32% | 50% |
| Family history | Yes:No | 9:34 | 4:15 | 5:19 |
| History of status | Yes:No | 16:27 | 6:13 | 10:14 |
| EEG | Normal | 2 | 1 | 1 |
| | Left sided | 11 | 5 | 6 |
| | Right sided | 8 | 3 | 5 |
| | Bilateral | 5 | 2 | 3 |
| | Generalised | 17 | 8 | 9 |
| Seizure type (N) | IA | 2 | 0 | 2 |
| | IB | 32 | 13 | 19 |
| | IC | 33 | 14 | 19 |
| | PG: | 5 | 4 | 1 |
| | IIA | 0 | 0 | 0 |
| | IIB | 0 | 0 | 0 |
| | IID | 0 | 0 | 0 |
| | IIE | 5 | 4 | 1 |
| | IIF | 2 | 1 | 1 |
| Number of seizure types | 1 | 11 | 5 | 6 |
| | 2 | 30 | 14 | 16 |
| | 3 | 2 | 0 | 2 |

Key: IA, simple partial; IB, complex partial; IC, secondary generalised; PG, primary generalised; IIA, absense; IIB, myoclonic; IID, tonic; IIE, tonic-clonic; IIF, atonic; SD, standard deviation

Note: numbers do not add up as number of patients had more than one seizure type.

Table 6.2: Medication details: patients with complete data only (all 4 occasions).

| AED | Statistic | All patients N=43 | Study 1 N=19 | Study 2 N=24 |
|---|---|---|---|---|
| PHT | N | 19 | 11 | 8 |
| | Mean (SD) | 367 (68.7) | 366 (68.3) | 369 (74.1) |
| | Median (Range) | 350 (275-500) | 350 (275-500) | 350 (275-500) |
| CBZ | N | 27 | 9 | 18 |
| | Mean (SD) | 1259 (358.7) | 1267 (387.3) | 1256 (355.2) |
| | Median (Range) | 1200 (800-1800) | 1200 (800-1800) | 1200(800-1800) |
| VPA | N | 13 | 7 | 6 |
| | Mean (SD) | 1885 (546) | 1929 (608) | 1833 (516) |
| | Median (Range) | 2000 (1000-3000) | 2000 (1000-3000) | 2000(1000-2500) |
| PB | N | 2 | 1 case only: | 1 case only: |
| | Mean (SD) | 135 (21.2) | 150 mg daily | 120 mg daily |
| | Median (Range) | 135 (120-150) | | |
| PRM | N | 13 | 6 | 7 |
| | Mean (SD) | 677 (320.6) | 833 (302.8) | 543 (289.3) |
| | Median (Range) | 750 (50-1250) | 875 (500-1250) | 750 (50-750) |
| ETH | N | 1 case only: | 1 case only: | No cases |
| | Mean (SD) | 500 mg daily | 500 mg daily | |
| | Median (Range) | | | |
| CLB | N | 12 | 3 cases: all | 9 |
| | Mean (SD) | 12.9 (6.9) | 10 mg daily | 12.8 (7.5) |
| | Median (Range) | 10.0 (5-30) | | 10 (5-30) |
| Co-med (non-AED) | | | | |
| | Yes:No | 27:16 | 14:5 | 13:11 |
| Mono:polytherapy | | | | |
| | No. of cases | 11:32 | 5:14 | 6:18 |

N,number of patients; PHT, phenytoin; CBZ, carbamazepine; VPA, sodium valproate; PB, phenobarbitone; PRM, primidone; ETH, ethosuximide; CLB, clobazam; Co-med, co-medication; AED, antiepileptic drug; SD, standard deviation.

### 6.1.c Trigeminal neuralgia patients: Study 3

19 patients were entered into the study, of whom 14 completed pre-and post-surgery assessments. The remaining 5 patients elected not to undergo surgery for this condition. Of the 14 patients who completed the study, 3 were excluded from the analysis due to missing data (did not complete all sections of the repertory grid). 8 patients had total relief of pain following surgery (SUCCESS group) and 3 were deemed to be surgery failures ie. still in considerable pain following surgery or with complications (FAILURE group). Basic patient information is listed in Table 6.3. The majority of patients were taking medication prior to surgery, the most commonly prescribed drug being carbamazepine (see Table 6.4). The group in whom operation was not successful were significantly older than the success group ($t=2.62$, $p<.047$).

Table 6.3: Trigeminal neuralgia group - basic details, completed patients (n=11).

| ID | Age | Sex | Duration of TN (yrs) | Age of onset | Side/type of op. | Medication Pre-op | Medication Post-op | Int1 | Int2 | Outcome |
|---|---|---|---|---|---|---|---|---|---|---|
| 02 | 44 | M | 5 | 39 | Left RFT | no | no | 146 | 49 | Success |
| 04 | 56 | M | 12 | 44 | Right RFT | yes | yes | 34 | 121 | Failure |
| 05 | 43 | M | 4 | 39 | Right MVD | yes | no | 32 | 184 | Success |
| 06 | 42 | F | 14 | 28 | Right MVD | yes | yes | 75 | 67 | Success |
| 07 | 41 | F | 3 | 38 | Right MVD | yes | no | 63 | 81 | Success |
| 10 | 72 | F | 12 | 60 | Right RFT | yes | no | 62 | 68 | Success |
| 12 | 28 | F | 3 | 25 | Right MVD | yes | no | 47 | 35 | Success |
| 14 | 51 | M | 10 | 41 | Right RFT | no | no | 27 | 61 | Success |
| 16 | 60 | M | 8 | 52 | Left RFT | yes | no | 256 | 19 | Success |
| 18 | 75 | F | 11 | 64 | Right RFT | yes | no | 145 | 70 | Failure |
| 20 | 70 | M | 26 | 44 | Left RFT | yes | no | 7 | 28 | Failure |

M, male; F, female; Int1, interval (in days) between 1st assessment and operation; Int2, interval (days) between operation and post-op assessment; RFT, radiofrequency thermocoagulation; MVD, microvascular decompression.

Table 6.4: Details of pre and post-operative medications for trigeminal neuralgia group (n=11).

| ID | MEDICATION (daily dose) | |
|---|---|---|
| | Pre-op | Post-op |
| 02 | No drugs | No drugs |
| 04 | CBZ, 800 mg | CBZ, 200mg; PRT, 50 mg |
| 05 | CBZ, 1000-1200 mg | No drugs |
| 06 | CBZ, 1200 mg | PRT, 150 mg |
| 07 | CBZ, 1400 mg | No drugs |
| 10 | PHT, 1200 mg | No drugs |
| 12 | CBZ, 1000mg | No drugs |
| 14 | No drugs | No drugs |
| 16 | CBZ, 1000mg | No drugs |
| 18 | CBZ, 600 mg | No drugs |
| 20 | CBZ, 1200 mg | No drugs |

CBZ, carbamazepine, PRT, prothiaden; PHT, phenytoin

# CHAPTER 6

# RESULTS

## 6.2. PSYCHOMETRIC PROPERTIES OF RG MEASURES

## 6.2. PSYCHOMETRIC PROPERTIES OF REPERTORY GRID MEASURES

Full details of frequency measures (mean, SD, median, range) for the repertory grid measures (aggregate, profile method 1, profile method 2) can be found in Appendix 17.

### 6.2.a Aggregate RG measures

#### 6.2.a.i Influence of age and IQ

Session 1 data were analysed to assess the influence of demographic factors such as age and IQ on the aggregate RG measures. The only significant correlation seen was between ABS6 and WAIS full-scale IQ ($r=.36$, $p<.01$). All other measures (DIR, ABS6, DIR6, ABS21) showed low, non-significant correlations with age and intellectual level (See Table 6.5).

#### 6.2.a.ii Influence of gender

Analysis of variance of the aggregate RG measures by gender produced no significant findings, indicating that these measures are not unduly influenced by the sex of the patients (see Appendix 18). Due to the preponderance of males in the epilepsy group as a whole, the influence of gender was further investigated in a sub-group of matched patients (n=18). The 9 female patients in the group were individually matched to 9 male patients for age, IQ and seizure type. The demographic details of these matched groups are listed in Table 6.6. With regard to medication taken, carbamazepine was the most commonly prescribed anticonvulsant, being taken by 6/9 in the female group and 5/9 in the male group. The majority of patients were receiving a combination of drugs (polytherapy); 7 patients were on monotherapy with either CBZ (n=4), PRIM (n=2) or PHT (n=1).

In this more detailed analysis of the effect of gender, none of the aggregate RG measures showed any significant discrepancy based upon the sex of subjects (see Appendix 18 for full details).

Table 6.5: Correlations[a] of aggregate RG measures with age and IQ measures; epilepsy patients, session 1 data.

| | AGE (n=50) | | FSIQ (n=45) | | PIQ (n=45) | | VIQ (n=45) | |
|---|---|---|---|---|---|---|---|---|
| | r | p | r | p | r | p | r | p |
| ABS | -.15 | .30 | .12 | .45 | .16 | .29 | .18 | .23 |
| DIR | -.08 | .57 | .05 | .73 | .06 | .70 | .18 | .22 |
| ABS6 | .02 | .90 | .36 | .02 | .20 | .20 | .24 | .12 |
| DIR6 | .01 | .96 | .16 | .28 | .07 | .63 | .18 | .22 |
| ABS21 | -.12 | .42 | .25 | .10 | .11 | .46 | .19 | .22 |

[a] Pearsons r

Table 6.6: Gender effect: demographic details of matched groups (9 males:9females)

| Variable | FEMALE | MALE |
|---|---|---|
| Age: Mean (SD) | 46.9 (15.2) | 45.3 (11.8) |
| FSIQ: Mean (SD) | 91.8 (11.0) | 90.2 (7.6) |
| Qualifications: | | |
| None | 7 | 6 |
| CSE's/'O' levels | 0 | 1 |
| Vocational | 2 | 2 |
| Occupation: | | |
| Unemployed | 1 | 0 |
| Open employment | 0 | 0 |
| Sheltered employment | 7 | 9 |
| Retired | 1 | 0 |
| Age of onset (yrs) | | |
| Mean (SD) | 7.7 (5.3) | 11.7 (9.0) |
| Aetiology | | |
| Known | 4 | 5 |
| Not known | 5 | 4 |
| Seizure types | | |
| Simple partial | 0 | 2 |
| Complex partial | 8 | 7 |
| Secondary generalised | 6 | 8 |
| Primary generalised | 0 | 0 |
| Unclassified | 1 | 1 |

FSIQ, full-scale IQ; SD, standard deviation

6.2.a.iii **Temporal stability**

All epilepsy patients with complete RG data (n=43)

Full details of the inter-session correlation coefficients for all aggregate RG measures and all session pairings (S1vS2, S1vS3, S1vS4, S2vS3, S2vS4, S3vS4) are given in Table 6.7. A summary of these data by aggregate RG measure and time interval can be found in Tables 6.8 and 6.9 respectively. A wide variation is seen between the various measures. The non-ranked variables (ABS, DIR) show high and significant correlations across all time periods suggesting good stability/reproducibility of scores. Of the ranked variables (ABS6, DIR6, ABS21), ABS21 demonstrated the strongest temporal stability (combined mean correlation across all session pairings, r=0.43, range=.30 to .56) (See Table 6.8). In particular, ABS21 shows good temporal stability across the shorter time intervals (S1vS2, S2vS3, S1vS3), as would be expected (See Table 6.8). ABS6 and DIR6 show similar test retest correlations (combined mean correlations, r=0.29 and 0.31 respectively) (Table 6.8). A hierarchy thus seems to exist with regard to temporal stability: ABS > DIR > ABS21 > DIR6 > ABS6.

Looking specifically at temporal stability for the varying time intervals, no apparent difference is seen with all time periods show modest test-retest correlations with mean coefficients ranging from .43 (S3 v S4, 3 month interval) to .55 (S1 v S3, 3 month interval) (Table 6.9).

Temporal stability by life event groupings (n=19)

It was hypothesised that higher inter-session correlations would be seen in patients experiencing no change in their lives, as measured by the non-reporting of life events. (Details of the life events reported by this sub-group of patients are listed in Appendix 4). In general, this hypothesis was supported (combined mean correlations, no life event group (NLE), r=0.54; all patients, r=0.50; life event group (LE), r=0.27) (Table 6.8). There were, however, differences among the aggregate RG measures regarding the discrepancy in temporal stabilities for the LIFE EVENT and NO LIFE EVENT groups. This discrepancy provides a crude measure

Table 6.7: Temporal stability of aggregate RG measures in patients with epilepsy (n=43).

| Session pairing | Time interval | | ABS | DIR | ABS6 | DIR6 | ABS21 |
|---|---|---|---|---|---|---|---|
| S1vS2 | 1 month | r | .77 | .72 | .15 | .40 | .44 |
| | | p | <.001 | <.001 | ns | <.01 | <.01 |
| S2vS3 | 2 months | r | .82 | .78 | .23 | .35 | .52 |
| | | p | <.001 | <.001 | ns | <.05 | <.001 |
| S1vS3 | 3 months | r | .77 | .75 | .40 | .28 | .56 |
| | | p | <.001 | <.001 | <.01 | .07 | <.001 |
| S3vS4 | 3 months | r | .70 | .65 | .30 | .22 | .30 |
| | | p | <.001 | <.001 | ns | ns | ns |
| S2vS4 | 5 months | r | .79 | .72 | .26 | .25 | .31 |
| | | p | <.001 | <.001 | ns | ns | ns |
| S1vS4 | 6 months | r | .71 | .68 | .40 | .33 | .45 |
| | | p | <.001 | <.001 | <.01 | <.05 | <.01 |

S1, Baseline; S2, 1 month; S3, 3 months; S4, 6 months.

Table 6.8: Aggregate RG measures: mean test retest correlations, averaged across all session pairings (epilepsy patients, n=43): Comparison of stability of individual aggregate measures.

| | MEAN[a] (RANGE) | | |
|---|---|---|---|
| | All epilepsy patients (n=43) | No life event (NLE) group (n=9) | Life event (LE) group (n=10) |
| ABS | 0.76 (0.70 to 0.82) | 0.71 (0.42 to 0.89) | 0.68 (0.57 to 0.84) |
| DIR | 0.72 (0.65 to 0.78) | 0.69 (0.39 to 0.89) | 0.64 (0.45 to 0.79) |
| ABS21 | 0.43 (0.30 to 0.56) | 0.63 (0.38 to 0.72) | 0.17 (-.22 to 0.66) |
| DIR6 | 0.31 (0.22 to 0.40) | 0.25 (-.11 to 0.69) | -0.10 (-.64 to 0.36) |
| ABS6 | 0.29 (0.15 to 0.40) | 0.42 (0.14 to 0.93) | -0.04 (-.55 to 0.35) |
| All ratings | 0.50 (0.15 to 0.82) | 0.54 (-.11 to 0.93) | 0.27 (-.64 to 0.84) |

[a] Higher correlation indicates greater temporal stability

Table 6.9: Aggregate RG measures: mean test retest correlations, averaged across all measures (all epilepsy patients, n=43): Comparision of stability over varying time intervals.

| | | MEAN[a] (RANGE) | | |
|---|---|---|---|---|
| Session pairing | Time interval | ALL (n=43) | NLE (n=9) | LE (n=10) |
| S1 v S2 | 1 month | .50 (.15, .77) | .62 ( .20, .89) | .48 ( .57, .84) |
| S2 v S3 | 2 months | .54 (.23, .82) | .63 ( .47, .76) | .77 ( .45, .79) |
| S1 v S3 | 3 months | .55 (.28, .77) | .46 (-.11, .81) | .24 (-.22, .66) |
| S3 v S4 | 3 months | .43 (.22, .70) | .24 (-.12, .42) | .24 (-.64, .36) |
| S2 v S4 | 5 months | .47 (.25, .79) | .61 ( .39, .80) | .21 (-.55, .35) |
| S1 v S4 | 6 months | .51 (.33, .71) | .68 ( .53, .93) | -.01 (-.64, .64) |
| All ratings | | .50 (.15, .82) | .54 (-.11, .93) | .32 (-.64, .84) |

[a] Higher correlation indicates greater temporal stability
ALL, all epilepsy patients; NLE, no life event group; LE, life event group.

Table 6.10: Aggregate RG measures: temporal stability by life event grouping, Study 1 patients.

| Session pairing | | NO LIFE EVENT GROUP (N=9) | | | | | LIFE EVENT GROUP (N=10) | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | | ABS | DIR | ABS6 | DIR6 | ABS21 | ABS | DIR | ABS6 | DIR6 | ABS21 |
| S1vS2 | r | .89 | .89 | .40 | .20 | .71 | .57 | .45 | .35 | .36 | .66 |
| | p | .001 | .001 | .29 | .60 | .03 | .08 | .19 | .32 | .30 | .04 |
| S2vS3 | r | .74 | .76 | .47 | .47 | .72 | .84 | .79 | .10 | -.11 | .63 |
| | p | .02 | .02 | .20 | .20 | .03 | 002 | .006 | .79 | .75 | .05 |
| S1vS3 | r | .81 | .81 | .17 | -.11 | .62 | .64 | .67 | -.17 | -.11 | .19 |
| | p | .008 | .008 | .66 | .78 | .07 | .04 | .04 | .63 | .77 | .59 |
| S3vS4 | r | .42 | .39 | .14 | -.12 | .38 | .77 | .68 | -.02 | -.02 | -.22 |
| | p | .25 | .30 | .72 | .76 | .32 | .009 | .03 | .96 | .97 | .53 |
| S2vS4 | r | .80 | .77 | .44 | .39 | .67 | .66 | .59 | .05 | -.09 | -.15 |
| | p | .009 | .01 | .24 | .30 | .05 | .04 | .07 | .90 | .80 | .67 |
| S1vS4 | r | .59 | .53 | .93 | .69 | .65 | .61 | .64 | -.55 | -.64 | -.11 |
| | p | .01 | .15 | .000 | .04 | .06 | .06 | .05 | .10 | .05 | .76 |

r, Pearson product moment correlation (listwise deletion used); S1, baseline; 2, 1 month; S3, 3 months; S4, 6 months.

to the extent to which the hypothesis is supported by the individual aggregate RG measures, with a high discrepancy indicating support for the hypothesis. Summaries of the mean test-retest coefficients averaged across all session pairings for the LIFE EVENT and NO LIFE EVENT groups are given in Table 6.8. The largest discrepancy was seen for the variables ABS21 (mean correlation discrepancy: r(NLE)-r(LE)= .46) and ABS6 (discrepancy: r(NLE)-r(LE)=0.46) followed by DIR6 (discrepancy: r(NLE)-r(LE)=0.35), DIR (discrepancy: r(NLE)-r(LE)=0.05) and ABS (discrepancy: r(NLE)-r(LE)=0.03) (see Table 6.8). Thus the hypothesis was supported by the ranked variables (ABS21, ABS6, DIR6) but not the non-ranked variables (ABS, DIR). Full details of all inter-session correlations by life event grouping are given in Table 6.10.

Table 6.9 contains summaries of the mean correlations for the various time intervals (ranging from 1 to 6 months), averaged across all aggregate RG measures. As the life event groupings (LIFE EVENT, NO LIFE EVENT) were determined by the occurrence of any life event, reported by the patient, during the 6 months of the study, the test-retest correlation of interest is that between S1 (Baseline) and S4 (6 months). It was hypothesised that the NO LIFE EVENT GROUP would demonstrate a higher test-retest correlation between S1 (Baseline) and S4 (6 months) than the LIFE EVENT group. A striking difference between the life event groups was seen (mean correlation (S1 v S4): NO LIFE EVENT group, r=0.69, range 0.53,.93; LIFE EVENT group, r=-.01, range -0.64, 0.64) with the NO LIFE EVENT group, as predicted, showing greater temporal stability.

### 6.2.a.iv **Validity**

Table 6.11 outlines the hypothesised MTMM correlations for the aggregate RG measures. Applying a Bonferroni correction for multiple comparisons based on each domain (general, physical, cognitive, emotional, social and economic/work), significance levels were adopted as follows: general, physical, cognitive and social domains, $p<.005$ (.05/10); social and economic/work,

Table 6.11 Validity of aggregate RG measures:multi-method, multi-trait matrix based on hypothesised correlations between specified measures. Baseline data (n=25).

| | | Aggregate RG measure | | | | |
|---|---|---|---|---|---|---|
| Domain | Variable | ABS | DIR | ABS6 | DIR6 | ABS21 |
| GENERAL | GRS1 | .33 | .32 | .58* | .33 | .55* |
| | SIP-TOT | .32 | .23 | .17 | .22 | .10 |
| PHYSICAL | GRS2 | .40 | .39 | .19 | .13 | .20 |
| | SIP-PHY | .22 | .24 | .29 | .17 | .10 |
| COGNITIVE | GRS3 | .39 | .41 | .44 | .28 | .49 |
| | SIP-AB | .37 | .26 | .37 | .26 | .29 |
| EMOTIONAL | GRS4 | .37 | .23 | .16 | -.06 | .14 |
| | MACL-D | .36 | .21 | .03 | .27 | .05 |
| | SIP-EM | .25 | .25 | -.01 | .23 | -.003 |
| SOCIAL | GRS5 | .44 | .41 | .13 | .22 | .17 |
| | SIP-SI | .22 | .15 | -.01 | .09 | -.04 |
| ECON/ | GRS6 | .22 | .07 | .07 | -.01 | .06 |
| WORK | GRS7 | .42 | .52* | .14 | .18 | .23 |
| | SIP-WK | .25 | .06 | .14 | .26 | .20 |

Single trait, multi-method correlations

* p<.01

SIP, Sickness Impact Profile; GRS, Global rating scale.
GRS2, satisfaction with physical abilities; SIP-PHY, SIP physical category score; GR3, satisfaction with cognitive abililties; SIP-AB, SIP alertness behaviour score; GRS4, satisfaction with emotional status; MACL-D, MACL depression score; SIP-EM, SIP emotions score; GRS5, satisfaction with social functioning; SIP-SI, SIP social interaction score; GRS6, satisfaction with employment; GRS7, satisfaction with finances; SIP-WK, SIP work score; GRS1, satisfaction with life in general; SIP-TOT, SIP total score.

Table 6.12: Aggregate RG measures: within-method correlations, Study 2 baseline data (n=25).

| | ABS | DIR | ABS6 | DIR6 | ABS21 |
|---|---|---|---|---|---|
| ABS | 1.0 | | | | |
| DIR | .89** | 1.0 | | | |
| ABS6 | .64** | .68** | 1.0 | | |
| DIR6 | .42 | .48 | .57* | 1.0 | |
| ABS21 | .78** | .77** | .92** | .53* | 1.0 |

* p<.01 ** p<.001

p<.003 (.05/15). None of the correlations were significant at these stringent levels, however, the magnitude and ordering of the correlations are of interest.

ABS6 and ABS21 correlated highly with an independent rating by the patient regarding their satisfaction with life in general (GRS1) (ABS6, r=0.58, p<.01; ABS21, r=0.55, p<.01). This suggests that these measures have some validity as latent measures of overall quality of life. The other aggregate RG measures (ABS, DIR, DIR6) showed modest correlations with GRS1 (mean correlation= 0.33). All aggregate RG measures, however, showed low correlations with the other independent measure of general functioning (the SIP total disability score).

Several other correlations are of interest. Modest correlations, ranging from 0.28 to 0.49 were seen between GRS3 (satisfaction with cognitive abilities) and the RG aggregate measures (ABS, DIR, ABS6, DIR6, ABS21). This may suggest that satisfaction with cognitive abilities has an influence on overall quality of life.

Financial status and emotions also appear to be important to overall quality of life. GRS7 (satisfaction with finances) showed a moderate correlation with the aggregate RG measure DIR (r=0.52), while GRS4 (satisfaction with emotional state) correlated with ABS (r=0.37, ns). As expected, high inter-measure correlations between the aggregate RG scores were seen (see Table 6.12).

6.2.a.v **Sensitivity**

Study 1 data: 2 out of the 5 variables (ABS6, ABS21) successfully discriminated between those patients who had experienced life events during the 6 months of the study and those who had not (ABS6, F=6.98, df=1, p<.017; ABS21, F=7.66, df=1, p<.013) (See Table 6.13 for summary).

Study 2 data: a summary of the correlations between life events and change in RG aggregate measures is given in Table 6.14. No significant correlation between LES scores and aggregate RG measure change scores were seen for any session pairing (see Appendices 19, 20, 21 and 22).

Table 6.13: Study 1 patients: Summary of discriminant ability of aggregate RG measures (n=19).

| Variable | F | p |
|---|---|---|
| ABS21 | 7.66 | .013 |
| ABS6 | 6.98 | .017 |
| ABS | 0.45 | .51 |
| DIR | 0.39 | .54 |
| DIR6 | 0.28 | .60 |

Table 6.14: Study 2 patients: summary of correlations between life events and change in RG aggregate scores (averaged across all session pairings). Epilepsy patients with complete data on all 4 occasions (n=24)

| | NEGATIVE EVENTS Mean (Range) | POSITIVE EVENTS Mean (Range) | TOTAL EVENTS Mean (Range) | DISCREPANCY SCORE Mean (Range) |
|---|---|---|---|---|
| ABS | .02 (-.40,.37) | -.07 (-.19,.09) | -.06 (-.33,.20) | -.003(-.21,.10) |
| DIR | .15 (-.17,.44) | -.08 (-.29,.04) | .04 (-.06,.27) | -.12 (-.40,.13) |
| ABS6 | .04 (-.34,.33) | .15 (-.02,.20) | .14 ( .03,.22) | .08 (-.16,.38) |
| DIR6 | .12 (-.12,.35) | -.006(-.36,.33) | .10 (-.06,.24) | -.14 (-.46,.34) |
| ABS21 | .08 (-.36,.40) | -.009(-.10,.14) | .08 (-.003,.15) | -.04 (-.40,.32) |
| TOTAL | .08 (-.40,.44) | -.003(-.36,.33) | .06 (-.003,.27) | -.04 (-.40,.38) |

NOTE: Means take sign of correlation into account

Study 3 data: the means and standard deviations of the aggregate RG measures obtained pre- and post-operatively are listed in Table 6.15. The absolute (ABS, ABS6) and directional (DIR, DIR6) measures were identical, thus details of absolute measures only are given.

All 3 aggregate RG measures (ABS, ABS6, DIR6) showed significant pre to post-operative changes in patients whose operation successfully relieved their trigeminal neuralgia. In contrast, no significant differences were seen for the small number of cases in whom operation was unsuccessful. Details of these results are given in Table 6.16.

Table 6.15: Means, standard deviations, medians and ranges of aggregate RG scores for trigeminal neuralgia patients, pre- and post-operatively.

| Statistic | | SUCCESS (N=8) | | FAILURE (N=3) | |
|---|---|---|---|---|---|
| | | Pre-op | Post-op | Pre-op | Post-op |
| ABS | Mean (SD) | 21.0 (8.6) | 4.4 (5.1) | 11.3 (2.5) | 14.3 (3.8) |
| | Med (Range) | 21.5 (5-34) | 3.5 (0-16) | 11.0 (9-14) | 16.0 (10-17) |
| ABS6 | Mean (SD) | 5.1 (0.64) | 3.9 (0.8) | 4.7 (1.2) | 5.0 (0) |
| | Med (Range) | 5.0 (4-6) | 3.8 (3-5) | 4.0 (4-6) | 5.0 (5-5) |
| ABS21 | Mean (SD) | 16.6 (2.7) | 10.2 (3.6) | 15.0 (6) | 15.7 (1.3) |
| | Med (Range) | 16.3 (14-21) | 10.5 (6-16) | 15.0 (9-21) | 15.5 (14.5-17) |

Table 6.16: Summary of results of paired t-tests comparing pre- and post-operative aggregate RG scores in patients with trigeminal neuralgia.

| | SUCCESS | | FAILURE | |
|---|---|---|---|---|
| | t | p | t | p |
| ABS | 5.26 | .001 | -1.30 | 0.32 |
| ABS21 | 4.71 | .002 | -0.21 | 0.86 |
| ABS6 | 3.42 | .011 | -0.50 | 0.67 |

Note: data from failure group shown for illustrative purposes only

### 6.2.b Profile RG measures: Methods 1 and 2

#### 6.2.b.i Influence of age and IQ

Age and intellectual level correlations were investigated using Session 1 (baseline, n=50) data. No significant correlations at the .01 level were seen between the profile RG measures (method 1 or method 2) and either age or IQ (See Table 6.17 for full details).

It should be noted, however, that a moderate correlation between emotional state (method 2) and full-scale and performance IQ was seen (FSIQ, $r=0.33$, $p<.04$; PIQ, $r=0.39$, $p<.012$).

#### 6.2.b.ii Influence of gender

All epilepsy patient data: analysis of variance of the profile RG measures (methods 1 and 2) by gender produced no significant findings, indicating that these measures are not unduly influenced by the sex of the patients (see Appendix 23 for details).

Matched group (n=18): the profile RG measures (methods 1 and 2) did not demonstrate any significant gender effects in this analysis (see Appendix 23 for details).

Table 6.17: Correlations[a] of profile RG measures with age and IQ measures; epilepsy patients, session 1 data.

| | AGE (n=50) | | FSIQ (n=45) | | PIQ (n=45) | | VIQ (n=45) | |
|---|---|---|---|---|---|---|---|---|
| | r | p | r | p | r | p | r | p |
| METHOD 1 | | | | | | | | |
| PHYS1 | -.09 | .55 | .11 | .49 | .10 | .51 | .14 | .37 |
| COG1 | -.004 | .98 | .11 | .45 | .11 | .48 | .14 | .36 |
| EMOT1 | -.15 | .29 | .17 | .26 | .24 | .11 | .19 | .22 |
| SOC1 | -.30 | .03 | .04 | .80 | .11 | .48 | .12 | .42 |
| WORK1 | -.14 | .35 | -.02 | .88 | .02 | .89 | .14 | .35 |
| METHOD 2 | | | | | | | | |
| PHYS2 | .04 | .79 | .20 | .23 | .18 | .17 | .08 | .63 |
| COG2 | .006 | .97 | .28 | .09 | .19 | .26 | .24 | .14 |
| EMOT2 | .06 | .71 | .33 | .04 | .39 | .012 | .27 | .10 |
| SOC2 | -.31 | .049 | .03 | .85 | .25 | .14 | .12 | .46 |
| WORK2 | -.01 | .95 | .08 | .62 | .23 | .17 | .01 | .97 |

[a] Pearsons

PHYS, physical profile score; COG, cognitive profile score; EMOT, emotional profile score; SOC, social functioning profile score; WORK, economic/employment profile score.

6.2.b.iii **Temporal stability**

Method 1 profile scores

Full details of the inter-session correlation coefficients for all profile RG measures (method 1) and all session pairings (S1vS2, S1vS3, S1vS4, S2vS3, S2vS4, S3vS4) are given in Table 6.18. Summaries of these data by individual RG measure (Table 6.19) and time interval (Table 6.20) are also given. Looking at the average correlations for each profile score, it can be seen that all profile RG scores (PHYS1, COG1, EMOT1, SOC1, WORK1) showed high test-retest correlations with an overall mean correlation (all scores, all sessions of 0.67 (range=.49 to .79) (Table 6.19). This suggests that the profile RG measures have reasonable temporal stability.

Regarding stability over differing time intervals (averaged across all profile measures), there appears to be little variation in time periods ranging from 1 to 6 months. High test-retest correlations were evident for all session pairings (S1vS2, S1vS3, S1vS4, S2vS3, S2vS4, S3vS4), with correlation coefficients ranging from .59 (S1vS4, time interval 6 months) to .72 (S2vS3, time interval 2 months) (Table 6.20).

Further evidence of temporal stability was provided by the analysis of the epilepsy patients by life event groups (no life event versus life event groups). Summaries of the test-retest correlations for the LIFE EVENT and NO LIFE EVENT groups are given in Tables 6.19 (by profile measure) and 6.20 (by inter-session interval) with full details to be found in Table 6.21.

Expected trends were seen for the profile RG measures (overall mean correlations: NO LIFE EVENT group, r=0.69, range .35 - .93; ALL PATIENTS, r=0.67, range .49 - .79; LIFE EVENT group, r=.53, range .13 - .94) (see Table 6.19), with little difference being seen between the various profile measures. This ordering of groups in relation to temporal stability is similar to that seen with the aggregate measures, however, the discrepancy between the LIFE EVENT and NO LIFE EVENT groups is smaller. This suggests that these scores (profile RG measures)

Table 6.18: Profile RG measures (method 1): temporal stability coefficients, epilepsy group, all patients with data on 4 occasions (n=43)

| Session pairing | Time interval | | PROFILE MEASURE | | | | |
|---|---|---|---|---|---|---|---|
| | | | Phys1 | Cog1 | Emot1 | Soc1 | Work1 |
| S1 v S2 | 1 month | r | .49 | .62 | .74 | .69 | .76 |
| | | p | .001 | .000 | .000 | .000 | .000 |
| S2 v S3 | 2 months | r | .79 | .65 | .76 | .68 | .74 |
| | | p | .000 | .000 | .000 | .000 | .000 |
| S1 v S3 | 3 months | r | .55 | .77 | .71 | .64 | .79 |
| | | p | .000 | .000 | .000 | .000 | .000 |
| S3 v S4 | 3 months | r | .74 | .57 | .64 | .70 | .69 |
| | | p | .000 | .000 | .000 | .000 | .000 |
| S2 v S4 | 5 months | r | .59 | .64 | .77 | .67 | .71 |
| | | p | .000 | .000 | .000 | .000 | .000 |
| S1 v S4 | 6 months | r | .53 | .63 | .56 | .57 | .66 |
| | | p | .000 | .000 | .000 | .000 | .000 |

S1, Baseline; S2, 1 month; S3, 3 months; S4, 6 months; r, Pearsons correlation coefficient; p, 2-tailed significance; Phys1, physical functioning; Cog1, cognitive abilities; Emot1, emotional status; Soc1, social functioning; Work1, economic/employment situation.

Table 6.19: Profile RG measures (method 1): mean test retest correlations, averaged across all session pairings: comparison of stability of individual profile scores.

| | MEAN[a] (RANGE) | | | | | |
|---|---|---|---|---|---|---|
| | All epilepsy patients (n=43) | | No life event (NLE) group (n=9) | | Life event (LE) group (n=10) | |
| PHYS1 | .62 | (.49 - .79) | .75 | (.54 - .93) | .40 | (.13 - .77) |
| COG1 | .65 | (.57 - .77) | .68 | (.35 - .88) | .52 | (.33 - .76) |
| EMOT1 | .70 | (.56 - .77) | .75 | (.63 - .90) | .51 | (.28 - .73) |
| SOC1 | .66 | (.57 - .70) | .69 | (.51 - .87) | .48 | (.21 - .76) |
| WORK1 | .73 | (.66 - .79) | .60 | (.36 - .83) | .73 | (.61 - .94) |
| All ratings | .67 | (.49 - .79) | .69 | (.35 - .93) | .53 | (.13 - .94) |

[a] Higher correlation indicates greater temporal stability

Table 6.20: Profile RG measures (method 1): mean test retest correlations, averaged across all profile measures: comparison of stability over varying time intervals.

| Session pairing | Time interval | MEAN[a] (RANGE) ALL (n=43) | NLE (n=9) | LE (n=10) |
|---|---|---|---|---|
| S1 v S2 | 1 month | .66 (.49 - .74) | .80 (.54 - .90) | .39 (.13 - .72) |
| S2 v S3 | 2 months | .72 (.65 - .79) | .67 (.58 - .80) | .68 (.34 - .94) |
| S1 v S3 | 3 months | .69 (.55 - .79) | .72 (.61 - .85) | .54 (.18 - .76) |
| S3 v S4 | 3 months | .67 (.57 - .74) | .61 (.35 - .93) | .66 (.58 - .76) |
| S2 v S4 | 5 months | .68 (.59 - .77) | .78 (.74 - .86) | .43 (.21 - .66) |
| S1 v S4 | 6 months | .59 (.53 - .66) | .57 (.36 - .71) | .46 (.28 - .71) |
| All ratings | | .67 (.49 - .79) | .69 (.35 - .93) | .53 (.13 - .94) |

[a] Higher correlation indicates greater temporal stability
ALL, all epilepsy patients; NLE, no life event group; LE, life event group.

Table 6.21: Profile RG scores (method 1): temporal stability by life event grouping, Study 1 patients.

| Session pairing | | NO LIFE EVENT GROUP (N=9) PHYS1 | COG1 | EMOT1 | SOC1 | WORK1 | LIFE EVENT GROUP (N=10) PHYS1 | COG1 | EMOT1 | SOC1 | WORK1 |
|---|---|---|---|---|---|---|---|---|---|---|---|
| S1 v S2 | r | .54 | .88 | .90 | .87 | .83 | .13 | .33 | .41 | .35 | .72 |
| | p | .13 | .002 | .001 | .002 | .006 | .72 | .34 | .24 | .33 | .02 |
| S2 v S3 | r | .80 | .62 | .70 | .66 | .58 | .61 | .76 | .73 | .34 | .94 |
| | p | .01 | .08 | .04 | .05 | .10 | .06 | .01 | .02 | .33 | .00 |
| S1 v S3 | r | .76 | .85 | .76 | .61 | .64 | .18 | .70 | .53 | .55 | .76 |
| | p | .02 | .004 | .02 | .08 | .06 | .61 | .02 | .11 | .10 | .01 |
| S3 v S4 | r | .93 | .35 | .66 | .70 | .43 | .77 | .60 | .58 | .76 | .61 |
| | p | .000 | .35 | .06 | .03 | .24 | .007 | .07 | .08 | .01 | .06 |
| S2 v S4 | r | .74 | .76 | .86 | .81 | .74 | .36 | .38 | .53 | .21 | .66 |
| | p | .02 | .02 | .003 | .008 | .02 | .31 | .27 | .12 | .57 | .04 |
| S1 v S4 | r | .71 | .64 | .63 | .51 | .36 | .33 | .35 | .28 | .64 | .71 |
| | p | .03 | .06 | .07 | .16 | .34 | .36 | .32 | .43 | .04 | .02 |

r, Pearson product moment correlation (listwise deletion); p, 2-tailed probability; S1, baseline, S2, 1 month; S3, 3 months; S4, 6 months; PHYS1, physical functioning profile score; COG1, cognitive abilities profile score; EMOT1, emotional status profile score; SOC1, social functioning profile score; WORK1, economic/employment situation profile score.

are more stable and are influenced by life events to a lesser extent than the aggregate scores.

Looking at the S1 v S4 correlation, there is little difference between the NO LIFE EVENT and LIFE EVENT groups (NO LIFE EVENT, r=.57, range .36 - .71; LIFE EVENT, r=.46, range .28 - .71) (see Table 6.20). While the trend was in the expected direction (that is, NO LIFE EVENT group to have higher correlation) and the LIFE EVENT group showed greater variability, the discrepancy between these groups was much less than that seen for the aggregate measures.

Method 2 profile scores

Profile scores calculated by method 2 demonstrated high inter-session stability across all session pairings, similar to those seen with the method 1 profile scores. Full details are given in Tables 6.22 (all session pairings), 6.23 (summarised by profile score) and 6.24 (summarised by time interval between sessions).

Temporal stability in general appears to be high, although some variation among the profile measures was noted (see Table 6.22). The highest coefficients were seen for the cognitive and economic/employment domains (Mean coefficients: COG2, r=0.64; WORK2, r=0.65), with the lowest correlation being seen in the emotional domain (EMOT2, r=0.46).

Looking at the mean correlations for the various time intervals (summed over the 5 domains, see Table 6.24) there is evidence to suggest that the profile scores possess good temporal stability across a wide range of time periods. As expected, the higher correlations are seen for the shorter time periods (1 month, r=0.62; 2 months, r=0.60) with a gradual decrease in test-retest correlation coefficients up to an test-retest interval of 6 months (r=0.47).

Full details of the temporal stability by life event groupings for method 2 profile scores are given in Table 6.25. Summaries by profile score domain and test-retest interval are to be found in Tables 6.23 and 6.24 respectively.

In general, the data do not follow the expected trend of higher correlations for the no life event group. The total

correlations for the 3 groupings do not differ greatly (mean correlations: all patients, r=0.57; no life event group, r=0.54; life event group, r=0.51; see Table 6.23 for details).

The trend does, however, hold for 3 out of the 5 scores (PHYS2, COG2, and EMOT2) where lower correlations are seen in the life event group (PHYS2, no life event r=0.73, life event r=0.40; COG2, no life event r=0.70, life event r=0.56; EMOT2, no life event r=0.49, life event r=0.37: see Table 6.22). However, for SOC2 and WORK2 the trend is reversed, with higher correlations being seen in the life event group.

The data relating to temporal stability across all time periods (summed over profile scores; see Table 6.24) show no definite trends. Variations in the temporal stability of the individual profile measures and timing of life events may make interpretation of these data difficult.

Table 6.22: Profile RG measures (method 2): temporal stability coefficients, epilepsy group, all patients with data on 4 occasions (n=43)

| Session pairing | Time interval | | PROFILE MEASURE | | | | |
|---|---|---|---|---|---|---|---|
| | | | Phys2 | Cog2 | Emot2 | Soc2 | Work2 |
| S1 v S2 | 1 month | r | .53 | .63 | .58 | .59 | .75 |
| | | p | .000 | .000 | .000 | .000 | .000 |
| S2 v S3 | 2 months | r | .69 | .61 | .56 | .55 | .60 |
| | | p | .000 | .000 | .000 | .000 | .000 |
| S1 v S3 | 3 months | r | .55 | .75 | .49 | .46 | .74 |
| | | p | .000 | .000 | .001 | .002 | .000 |
| S3 v S4 | 3 months | r | .68 | .61 | .35 | .59 | .65 |
| | | p | .000 | .000 | .02 | .000 | .000 |
| S2 v S4 | 5 months | r | .48 | .56 | .55 | .54 | .59 |
| | | p | .001 | .000 | .000 | .000 | .000 |
| S1 v S4 | 6 months | r | .56 | .65 | .25 | .35 | .56 |
| | | p | .000 | .000 | .10 | .02 | .000 |

S1, Baseline; S2, 1 month; S3, 3 months; S4, 6 months.
r, Pearsons correlation coefficient; p, 2-tailed significance.
Phys2, physical functioning; Cog2, cognitive abilities; Emot2, emotional status; Soc2, social functioning; Work2, economic/employment situation.

Table 6.23: Profile RG measures (method 2): mean test retest correlations, averaged across all session pairings: comparison of stability of individual profile scores.

| | MEAN[a] (RANGE) | | | | | |
|---|---|---|---|---|---|---|
| | All epilepsy patients (n=43) | | No life event (NLE) group (n=9) | | Life event (LE) group (n=10) | |
| PHYS2 | .58 | (.48 - .69) | .73 | (.43 - .91) | .40 | (.00 - .83) |
| COG2 | .64 | (.56 - .75) | .70 | (.47 - .93) | .56 | (.31 - .79) |
| EMOT2 | .46 | (.25 - .58) | .49 | (.28 - .88) | .37 | (.00 - .68) |
| SOC2 | .51 | (.35 - .59) | .32 | (-.03 - .73) | .46 | (.23 - .73) |
| WORK2 | .65 | (.56 - .75) | .48 | (.32 - .73) | .74 | (.56 - .91) |
| All ratings | .57 | (.25 - .75) | .54 | (-.03 - .93) | .51 | (.00 - .91) |

[a] Higher correlation indicates greater temporal stability

Table 6.24: Profile RG measures (method 2): mean test retest correlations, averaged across all profile measures: comparison of stability over varying time intervals.

| Session pairing | Time interval | MEAN[a] (RANGE) ALL (n=43) | NLE (n=9) | LE (n=10) |
|---|---|---|---|---|
| S1 v S2 | 1 month | .62 (.53 - .75) | .72 (.43 - .88) | .43 (.00 - .85) |
| S2 v S3 | 2 months | .60 (.55 - .69) | .56 (.29 - .86) | .60 (.37 - .91) |
| S1 v S3 | 3 months | .60 (.46 - .75) | .50 (.04 - .93) | .65 (.47 - .80) |
| S3 v S4 | 3 months | .58 (.35 - .68) | .52 (.28 - .91) | .56 (.00 - .83) |
| S2 v S4 | 5 months | .54 (.48 - .59) | .59 (.52 - .73) | .35 (.17 - .64) |
| S1 v S4 | 6 months | .47 (.25 - .65) | .37 (-.03- .79) | .44 (.01 - .69) |
| All ratings | | .57 (.25 - .75) | .54 (-.03- .93) | .51 (.00 - .91) |

[a] Higher correlation indicates greater temporal stability

ALL, all epilepsy patients; NLE, no life event group; LE, life event group;

Table 6.25: Profile RG scores (method 2): temporal stability by life event grouping, Study 1 patients.

| Session pairing | | NO LIFE EVENT GROUP (N=9) PHYS2 | COG2 | EMOT2 | SOC2 | WORK2 | LIFE EVENT GROUP (N=10) PHYS2 | COG2 | EMOT2 | SOC2 | WORK2 |
|---|---|---|---|---|---|---|---|---|---|---|---|
| S1 v S2 | r | .43 | .85 | .88 | .73 | .73 | .003 | .42 | .56 | .30 | .85 |
| | p | .25 | .003 | .002 | .027 | .026 | .99 | .23 | .10 | .40 | .002 |
| S2 v S3 | r | .86 | .79 | .50 | .29 | .38 | .42 | .62 | 68 | .37 | .91 |
| | p | .003 | .012 | 18 | .44 | .32 | .23 | .054 | 03 | .29 | .000 |
| S1 v S3 | r | .67 | .93 | .52 | .04 | .32 | .47 | .79 | .58 | .61 | .80 |
| | p | .049 | .000 | .15 | .92 | .41 | .17 | .007 | .08 | .06 | .005 |
| S3 v S4 | r | .91 | .50 | .28 | .33 | 58 | .83 | .70 | .00 | .73 | .56 |
| | p | .001 | .17 | .47 | .39 | .11 | .003 | .026 | 1.0 | .02 | .09 |
| S2 v S4 | r | .73 | .63 | .52 | .57 | .51 | .17 | .31 | .40 | .23 | .64 |
| | p | .02 | .07 | .15 | .11 | .16 | .64 | .38 | .25 | .51 | .04 |
| S1 v S4 | r | .79 | .47 | .31 | -.03 | 33 | 50 | .51 | .01 | .49 | .69 |
| | p | .01 | .21 | .41 | .94 | .38 | 14 | .13 | .98 | .15 | .03 |

S1, Baseline; S2, 1 month; S3, 3 months; S4, 6 months.
r, Pearsons correlation coefficient (listwise deletion); p, 2-tailed significance; PHYS2, physical functioning; COG2, cognitive abilities; EMOT2, emotional status; SOC2, social functioning; WORK2, economic/employment situation.

6.2.b.iv **Validity**

Method 1 profile scores

Table 6.26 outlines the expected MTMM correlations for the profile RG measures (method 1). As for the aggregate RG measures analysis, significance levels of .005 (general, physical, cognitive and social domains) and .003 (emotional and economic/work domains) were applied (Bonferroni corrections).

PHYS1 correlated poorly with the other measures of physical functioning (GRS2, r=0.25; SIP-Phys, r=0.29). In addition, a moderate correlation was seen with SIP-Emotions (r=0.41) and high correlations with several of the aggregate RG measures (DIR, r=0.61; ABS, r=0.59; ABS21, r=0.54; ABS6, r=0.45). The correlation with a measure of emotional state may reflect the fact that the PHYS1 score often contained a construct related to having epilepsy, for example, 'Having fits' or 'Having epilepsy'. Epilepsy is not a simple physical illness and this finding may reflect the emotional impact that having epilepsy produces in an individual.

The cognitive profile score (COG1) correlated well with other indices of cognitive status (GRS3, r=0.61; SIP-AB, r=0.44). The RG-based measure of cognitive functioning also correlated with measures of general life satisfaction (GRS1, r=0.47), financial status (GRS7, r=0.44) and social functioning (GRS5, r=0.40). High correlations with all aggregate RG measures were also seen (see Table 6.26).

EMOT2 correlated well with 2 out of the 3 latent measures of emotional state used in the MTMM matrix (GRS4, r=0.46; MACL-Depression, r=0.39). With the exception of SIP-AB (r=0.40) all other correlations were lower than these (as predicted by the MTMM hypothesis). High correlations seen with the aggregate RG measures included ABS (r=0.84), ABS21 (r=0.68), DIR (r=0.53) and ABS6 (r=0.51).

The RG measure of social functioning (SOC1) showed slightly higher correlations with latent measures of emotional state (MACL-Depression, r=0.46; GRS4, r=0.37) than with measures of social function (GRS5, r=0.36; SIP-SI, r=0.30). This suggests that these 2 categories are closely identified by patients. Financial status as assessed by the variable GRS7

Table 6.26: Validity of profile RG measures (method 1): multimethod, multi-trait matrix based on hypothesised correlations between specified measures. Baseline data (n=25).

| | | Profile Score (method 1) | | | | |
|---|---|---|---|---|---|---|
| Domain | Variable | Phys1 | Cog1 | Emot1 | Soc1 | Work1 |
| PHYSICAL | GRS2 | .25 | .22 | .23 | .14 | .32 |
| | SIP-PHY | .29 | .18 | .08 | .03 | .05 |
| COGNITIVE | GRS3 | .15 | .61** | .25 | .27 | .29 |
| | SIP-AB | .14 | .44 | .40 | .20 | .14 |
| EMOTIONAL | GRS4 | .11 | .27 | .46 | .37 | .19 |
| | MACL-D | .08 | .25 | .39 | .46 | .14 |
| | SIP-EM | .41 | -.19 | .17 | .21 | .25 |
| SOCIAL | GRS5 | .17 | .40 | .34 | .36 | .26 |
| | SIP-SI | .19 | .06 | .23 | .30 | .14 |
| ECON/ | GRS6 | .12 | .21 | .20 | .23 | .18 |
| WORK | GRS7 | .03 | .44 | .14 | .34 | .35 |
| | SIP-WK | .16 | .19 | .20 | .06 | .31 |
| GENERAL | GRS1 | .25 | .47 | .32 | .19 | .17 |
| | SIP-TOT | .34 | .08 | .23 | .20 | .15 |
| | ABS | .59* | .76** | .84** | .70** | .84** |
| | DIR | .61** | .69** | .53* | .61** | .72** |
| | ABS6 | .45 | .65** | .51* | .17 | .52* |
| | DIR6 | .25 | .45 | .35 | .35 | .49 |
| | ABS21 | .54* | .78** | .68** | .43 | .75** |

Single trait, multi-method correlations

** p<.001 * p<.01

SIP, Sickness Impact Profile; GRS, Global rating scale.
GRS2, satisfaction with physical abilities; SIP-PHY, SIP physical category score; GR3, satisfaction with cognitive abililties; SIP-AB, SIP alertness behaviour score; GRS4, satisfaction with emotional status; MACL-D, MACL depression score; SIP-EM, SIP emotions score; GRS5, satisfaction with social functioning; SIP-SI, SIP social interaction score; GRS6, satisfaction with employment; GRS7, satisfaction with finances; SIP-WK, SIP work score; GRS1, satisfaction with life in general; SIP-TOT, SIP total score.

Table 6.27: Profile RG measures (method 1): within-method correlations, Study 2 baseline data (n=25).

| | PHYS1 | COG1 | EMOT1 | SOC1 | WORK1 |
|---|---|---|---|---|---|
| PHYS1 | 1.0 | | | | |
| COG1 | .14 | 1.0 | | | |
| EMOT1 | .44 | .41 | 1.0 | | |
| SOC1 | .46 | .36 | .49 | 1.0 | |
| WORK1 | .51* | .51* | .48 | .43 | 1.0 |

* p<.01 ** p<.001

correlated to a similar degree with SOC1 as the independent measures of social functioning (GRS7, r=0.34). It seems reasonable to predict/expect that social functioning depends to some extent upon financial status. Again, high correlations between this profile score and several aggregate RG scores were seen (ABS, r=0.70; DIR, r=0.61; ABS21, r=0.43) .

In general, moderate correlations were seen between the economic/employment profile score (WORK1) and the independent variables, although trends in the expected direction were evident. Among the non-RG measures, the highest correlations were with other measures of employment and finances (GRS7, r=0.35; SIP-WORK, r=0.31), as predicted by the MTMM approach. The same degree of correlation was seen with a measure of satisfaction with physical ability (GRS2, r=0.32). High correlations were seen with all aggregate RG measures (see Table 6.26).

Correlations between the profile scores (within-method) are given in Table 6.27. Moderate correlations ranging from .14 to .51 were seen. This may be due to method artefact or may represent the non-independence of the 5 domains.

Method 2 profile scores

The MTMM matrix for the profile scores (method 2) is shown in Table 6.28. The physical profile score (PHYS2) demonstrated only a modest correlation with one of the independent measures of physical functioning (SIP-Phys, r=0.33), however, correlations with measures of different traits were lower than this, providing some evidence of validity for this measure.

COG2 demonstrated a high correlation with an independent measure of cognitive ability (GRS3, r=0.68), indicating a degree of validity. This profile measure also showed moderate correlations with measures of social functioning (GRS4, r=0.42), finances (GRS7, r=0.53) and overall life satisfaction (GRS1, r=0.48). Similar correlations were noted for this profile measure when calculated by method 1. These should not be too surprising as cognitive ability is a fundamental function and likely to be associated with social functioning, ability to work and hence financial situation and life in general.

Table 6.28: Validity of profile RG measures (method 2): multi- method, multi-trait matrix based on hypothesised correlations between specified measures. Baseline data (n=25).

| | | Profile score (method 2) | | | | |
|---|---|---|---|---|---|---|
| Domain | Variable | Phys2 | Cog2 | Emot2 | Soc2 | Work2 |
| PHYSICAL | GRS2 | .03 | .30 | .08 | .32 | .52* |
| | SIP-PHY | .33 | .07 | -.13 | .10 | .15 |
| COGNITIVE | GRS3 | .008 | .68** | .10 | .25 | -.03 |
| | SIP-AB | .11 | .34 | . 6 | .20 | .16 |
| EMOTIONAL | GRS4 | .07 | .25 | .54* | .21 | .34 |
| | MACL-D | .15 | .17 | .34 | .29 | .15 |
| | SIP-EM | .12 | -.08 | .24 | .17 | .53* |
| SOCIAL | GRS5 | .10 | .43 | .31 | .32 | .21 |
| | SIP-SI | .18 | -.008 | .14 | .23 | .25 |
| ECON/ | GRS6 | .13 | .15 | -.005 | .15 | .28 |
| WORK | GRS7 | -.14 | .53* | -.03 | .47 | .46 |
| | SIP-WK | .07 | -.15 | -.15 | .27 | 07 |
| GENERAL | GRS1 | .22 | .48 | .08 | .16 | -.02 |
| | SIP-TOT | .30 | .06 | .18 | .21 | .32 |
| | ABS | .63** | .70** | .71** | .79** | .75** |
| | DIR | .62** | .71** | .61** | .78** | .69** |
| | ABS6 | .24 | .44* | .47** | .47** | .34 |
| | DIR6 | .07 | .28 | .33 | .47** | .31 |
| | ABS21 | .43* | .53** | .57** | .70** | .55** |

Single trait, multi-method correlations

** p<.001 * p<.01

SIP, Sickness Impact Profile; GRS, Global rating scale.
GRS2, satisfaction with physical abilities; SIP-PHY, SIP physical category score; GR3, satisfaction with cognitive abililties; SIP-AB, SIP alertness behaviour score; GRS4, satisfaction with emotional status; MACL-D, MACL depression score; SIP-EM, SIP emotions score; GRS5, satisfaction with social functioning; SIP-SI, SIP social interaction score; GRS6, satisfaction with employment; GRS7, satisfaction with finances; SIP-WK, SIP work score; GRS1, satisfaction with life in general; SIP-TOT, SIP total score.

Table 6.29: Profile RG measures (method 2): within-method correlations, Study 2 baseline data (n=24)#

| | PHYS2 | COG2 | EMOT2 | SOC2 | WORK2 |
|---|---|---|---|---|---|
| PHYS2 | 1.0 | | | | |
| COG2 | -.09 | 1.0 | | | |
| EMOT2 | -.001 | .13 | 1.0 | | |
| SOC2 | .25 | .38 | .11 | 1.0 | |
| WORK2 | .02 | .37 | .06 | .27 | 1.0 |

* p<.01 ** p<.001 # 1 subject with no cognitive constructs

EMOT2 correlated highly with GRS4 (satisfaction with emotional state, r=0.51). This was the highest of all the correlations, providing good evidence of validity. Another correlation of note was with SIP-AB (r=0.46), a measure of alertness behaviour.

Validity was not established for the social profile score (SOC2) which showed low correlations with the 2 other social measures (GRS5, r=0.32; SIP-SI, r=0.23). SOC2 correlated as highly with measures assessing a range of traits, as it did with other social functioning measures. For example, SOC2 correlated with satisfaction with physical ability (GRS2, r=0.32), depression (MACL-D, r=0.29), employment (SIP-WORK, r=0.27) and satisfaction with cognitive abilities (GRS3, r=0.25). Satisfaction with finances was the trait most highly associated with social life as measured by SOC2 (GRS7, r=0.47).

The profile score assessing economic/employment situation (WORK2) also demonstrated a range of correlations not strictly following the MTMM hypothesis. A moderate correlation was seen with one of the independent measures of economic/employment status (GRS7, satisfaction with finances, r=0.46). This provides some evidence of validity as this was higher than the majority of other correlations. However, higher correlations were seen with emotional state (SIP-EM, r=0.53) and satisfaction with physical ability (GRS2, r=0.52). These latter correlations are more likely to reflect the multidimensional nature of the economic/employment domain than to raise questions about the validity of the measure. For example, physical ability will obviously affect an individuals ability to work and the psychological/emotional effects of unemployment are well documented.

As seen with the profile scores calculated by method 1, high correlations were seen between the RG-based profile scores (PHYS2, COG2, EMOT2, SOC2, WORK2) and the RG-based aggregate measures (ABS, DIR, ABS6, DIR6, ABS21 (see Table 6.28).

Table 6.29 outlines the within-method correlations for the profile scores. In contrast to method 1, which showed moderately high correlations between the profile measures,

method 2 profile scores general show low correlations with each other. The highest correlations were between cognitive ability (COG2) and social functioning (SOC2, r=0.38) and economic/employment status (WORK2, r=0.37). This is interesting as in the MTMM analysis cognitive ability (COG2) correlated with independent measures of social functioning (GRS4) and finances (GRS7).

This difference between the methods probably reflects the different methodologies employed. In method 1 a construct could be weighted on more than one profile domain, while in method 2 each construct was restricted to one domain only.

6.2.b.v **Sensitivity**

Method 1 profile scores

Study 1 data: no profile measure (PHYS1, COG1, EMOT1, SOC1, WORK1) successfully distinguished between those patients who experienced a life event during the study and those who did not (See Table 6.30 for summary of the analysis of variance findings).

Study 2 data: full details of the correlations between profile scores (method 1) and LES scores (negative, positive, total and discrepancy scores) are given in Appendices 24 - 27. These data are summarised in Table 6.31. Summed over all session pairings, no significant correlation between the profile measures (PHYS1, COG1, EMOT1, SOC1, WORK1) and LES scores was evident. The mean correlations were low ranging from -.09 (discrepancy score) to 0.12 (negative life events score) (see Table 6.31).

Study 3 data: profile scores (method 1) were not calculated for the trigeminal neuralgia patients.

Method 2 profile scores

Study 1 data: none of the profile measures calculated by method 2 successfully discriminated between those patients who had experienced a life event and those who had not (see Table 6.32 for details).

Study 2 data: no clear association between any of the profile scores and the LES measures was seen (see Table 6.33 for summary).

Study 3 data: 4 out of the 5 profile scores calculated by method 2 differentiated pre- and post-operative scores in patients who had undergone successful surgery for the relief of pain. Table 6.34 gives details of the pre- and post-operative profile scores for the successful and non-successful groups. Details of the statistical analyses can be found in Table 6.35.

Table 6.30: Study 1 patients: Summary of discriminant ability of profile RG measures (method 1) (Life event vs No life event groupings, n=19).

| Variable | F | p |
|---|---|---|
| PHYS1 | 1.64 | .22 |
| COG1 | .37 | .55 |
| EMOT1 | .02 | .89 |
| SOC1 | .85 | .37 |
| WORK1 | .30 | .59 |

PHYS1, physical profile score; COG1, cognitive profile score; EMOT1, emotional profile score; SOC1, social profile score; WORK1, economic/employment profile score.

Table 6.31: Summary of correlations between life events and change in profile RG scores (method 1)(averaged across all session pairings). Epilepsy patients with complete data on all 4 occasions (n=24)

| | NEGATIVE EVENTS Mean (Range) | POSITIVE EVENTS Mean (Range) | TOTAL EVENTS Mean (Range) | DISCREPANCY SCORE Mean (Range) |
|---|---|---|---|---|
| PHYS1 | .09 (-.14, .43) | -.15 (-.36, .05) | -.02 (-.23, .25) | -.08 (-.31, .14) |
| COG1 | .20 (-.20, .56) | -.19 (-.38, .05) | -.05 (-.36, .26) | -.28 (-.41,-.12) |
| EM1 | .27 ( .02, .41) | .03 (-.17, .31) | .13 (-.10, .49) | -.06 (-.22, .05) |
| SOC1 | .07 (-.10, .25) | -.04 (-.18, .20) | .03 (-.05, .17) | -.06 (-.25, .14) |
| WRK1 | -.01 (-.18, .16) | .06 (-.08, .22) | .08 (-.06, .27) | .05 (-.17, .21) |
| TOT | .12 (-.21, .56) | -.06 (-.38, .31) | .03 (-.36, .49) | -.09 (-.41, .21) |

PHYS1, physical score; COG1, cognitive score; EM1, emotions score; SOC1, social functioning score; WRK1, economic/employment score.

Table 6.32: Study 1 patients: Summary of discriminant ability of profile RG measures (method 2) (Life event vsno life event groupings, n=19).

| Variable | Z | p |
|---|---|---|
| PHYS2 | -1.08 | .28 |
| COG2 | -.54 | .59 |
| EMOT2 | -.96 | .34 |
| SOC2 | -.33 | .74 |
| WORK2 | -.34 | .74 |

PHYS2, physical profile score; COG2, cognitive profile score; EMOT2, emotional profile score; SOC2, social profile score; WORK2, economic/employment profile score.

Table 6.33: Summary of correlations between life events and change in profile RG scores (method 2)(averaged across all session pairings). Epilepsy patients with complete data on all 4 occasions (n=24)

| | NEGATIVE EVENTS Mean (Range) | POSITIVE EVENTS Mean (Range) | TOTAL EVENTS Mean (Range) | DISCREPANCY SCORE Mean (Range) |
|---|---|---|---|---|
| PHYS2 | .06 (-.15, .37) | .11 (-.04, .17) | .17 ( .02, .39) | .10 (-.15, .39) |
| COG2 | .14 (-.28, .50) | -.22 (-.37, .10) | -.11 (-.39, .30) | -.26 (-.46,-.08) |
| EM2 | .25 ( .02, .38) | .07 (-.14, .32) | .16 (-.01, .48) | -.07 (-.23, .15) |
| SOC2 | .11 (-.07, .32) | -.09 (-.40, .04) | -.03 (-.18, .16) | -.13 (-.44, .06) |
| WRK2 | .09 (-.06, .24) | .10 (-.09, .16) | .17 ( .05, .29) | -.01 (-.14, .12) |
| TOT | .13 (-.15, .50) | .006 (-.37, .32) | .07 (-.39, .48) | -.07 (-.44, .39) |

PHYS2, physical score; COG2, cognitive score; EM2, emotions score; SOC2, social functioning score; WRK2, economic/employment score.
NOTE: Means take sign of correlation into account

Table 6.34: Means, standard deviations, medians and ranges of RG profile scores (method 2) for trigeminal neuralgia patients, pre- and post-operatively.

| Statistic | | SUCCESS (N=8) Pre-op | SUCCESS (N=8) Post-op | FAILURE (N=3) Pre-op | FAILURE (N=3) Post-op |
|---|---|---|---|---|---|
| PHYS2 | Mean (SD) | 5.63 (12.0) | .75 (1.0) | 5.33 (2.1) | 4.67 (2.1) |
| | Med (Range) | 6.00 (5-34) | .50 (0-3) | 6.0 (3-7) | 4.0 (3-7) |
| COG2 | Mean (SD) | 4.0 (2.3) | 1.1 (1.5) | 1.67 (0.6) | 2.33 (1.5) |
| | Med (Range) | 4.0 (1-7) | 0.5 (0-4) | 2.00 (1-2) | 2.00 (1-4) |
| EMOT2 | Mean (SD) | 4.25 (2.6) | 0.9 (1.3) | 2.67 (1.2) | 2.33 (2.3) |
| | Med (Range) | 5.00 (1-7) | 0.5 (0-4) | 2.00 (2-4) | 1.00 (1-5) |
| SOC2 | Mean (SD) | 4.38 (2.3) | 0.5 (1.1) | 1.33 (1.2) | 2.33 (3.2) |
| | Med (Range) | 5.00 (0-7) | 0.0 (0-3) | 2.00 (0-2) | 1.00 (0-6) |
| WORK2 | Mean (SD) | 2.75 (2.6) | 1.1 (1.6) | 0.00 (0) | 2.33 (2.5) |
| | Med (Range) | 2.00 (0-6) | 1.0 (0-5) | 0.00 (0-0) | 2.00 (0-5) |

Table 6.35: Profile measures (method 2): results of paired t-tests comparing pre- and post-operative scores.

| SUCCESS GROUP (N=8) | | |
|---|---|---|
| Variable | t | p |
| PHYS2 | 6.57 | .000 |
| COG2 | 3.02 | .019 |
| EMOT2 | 4.47 | .003 |
| SOC2 | 5.06 | .001 |
| WORK2 | 1.80 | .116 |

PHYS2, physical profile score; COG2, cognitive profile score; EMOT2, emotional profile score; SOC2, social profile score; WORK2, economic/employment profile score.

NOTE: formal analyses not conducted on failure group due to small sample size (n=3)

# CHAPTER 6

# RESULTS

## 6.3 GENERAL PROPERTIES OF REPERTORY GRID DATA

## 6.3 GENERAL PROPERTIES OF REPERTORY GRID DATA

### 6.3.a Effect of standardising repertory grids

#### 6.3.a.i Comparision of rating methods: use of extreme ratings

The means and 95% confidence intervals (CI) of the calculated total deviation scores for all occasions are presented in Table 6.36. A consistent trend in the expected direction is seen. The highest scores are seen with the 100mm VAS (overall mean of 4 occasions=113.5; CI=106.8-120.3) and the lowest for the 1-5 Likert scale (overall mean of 4 occasions=101.5; CI=93.3-109.8) with the 1-10 Likert scale holding an intermediate position (overall mean of 4 occasions=103.1, CI=94.3-119.3). The overall means for both Likert scales (101.5 and 103.1) are below the lower limit of the 95% CI for the VAS scale (lower limit=106.8). This suggests a significant difference in the use of extremity ratings between these rating methods. Although these trends are moderately strong and in favour of the post-hoc hypothesis, formal inference testing in a repeated measures analysis of variance did not show a significant effect. There was no significant difference between rating methods ($F=1.67$, $df=2$, $p<.20$), occasions ($F=2.42$, $df=3$, $p<.08$) and no significant method by occasion interaction ($F=0.22$, $df=6$, $p<.97$).

### 6.3.b Construct and element stability

#### 6.3.b.i Element stability

Large between-subject differences in overall variability, with total grid variability values ranging from 7.6 to 92.3 (maximum possible range=0 to 371) were seen (see Table 6.37).

Details of the mean element variances are given in Table 6.38. The mean values are relatively low, given that the maximum possible variation for any one element is 53.3. While there is high between subject variation (mean element variances range from 0.0 to 41.0), the low overall means suggests that patients are actually fairly stable in their responses over time.

A significant agreement among patients relating to the ranking of the element variances was seen (Kendalls $W=0.40$, $X_2=103.2$, $df=6$, $p=.000$). It seems that while between-subject

Table 6.36: Means and 95% CI for total deviation scores, 4 occasions.

| Rating method | Statistic | Baseline | 1 month | 3 months | 6 months | Mean over 4 sessions |
|---|---|---|---|---|---|---|
| 0-100 VAS | Mean | 110.6 | 116.1 | 111.0 | 118.0 | 113.5 |
| | 95% CI | 104-117 | 108-124 | 101-121 | 110-126 | 106.8-120.3 |
| | | (n=8) | (n=8) | (n=8) | (n=7) | |
| 1-10 LIKERT | Mean | 104.6 | 106.9 | 102.2 | 105.0 | 103.1 |
| | 95% CI | 95.9-113 | 98.5-115 | 92.7-112 | 93.8-116 | 94.3-119.3 |
| | | (n=16) | (n=15) | (n=15) | (n=12) | |
| 1-5 IKERT | Mean | 102.1 | 105.4 | 103.8 | 106.7 | 101.5 |
| | 95% CI | 95.2-109 | 100-111 | 97.7-110 | 101-113 | 93.3-109.8 |
| | | (n=26) | (n=26) | (n=24) | (n=25) | |
| Overall | Mean | 104.3 | 107.6 | 104.5 | 108.0 | 103.8 |
| | 95% CI | 99.8-109 | 104-111 | 100-109 | 103-113 | 98.5-109.0 |

CI=confidence interval.

Data from epilepsy patients (Studies 1 and 2).

Table 6.37: Element variances by individual patient (43 epilepsy cases), listed in increasing order of total grid variability.

| | | ELEMENTS | | | | | | |
|---|---|---|---|---|---|---|---|---|
| ID | TOTAL | NOW | BEFORE | LIKE | EXPECT | FRIEND | BEST | WORST |
| 49 | 7.6 | 1.2 | 0.5 | 0.2 | 1.3 | 0.0 | 0.0 | 4.4 |
| 32 | 8.4 | 1.2 | 1.8 | 0.0 | 1.1 | 0.0 | 0.0 | 4.3 |
| 5 | 11.9 | 2.4 | 0.6 | 1.0 | 3.2 | 0.5 | 0.2 | 3.9 |
| 39 | 15.1 | 1.5 | 5.3 | 2.2 | 0.8 | 0.6 | 1.3 | 3.2 |
| 46 | 15.8 | 0.9 | 3.7 | 0.0 | 2.2 | 4.2 | 0.5 | 4.2 |
| 47 | 16.3 | 2.2 | 4.6 | 0.0 | 0.5 | 3.0 | 0.0 | 6.0 |
| 25 | 16.9 | 2.2 | 3.0 | 1.1 | 3.2 | 3.0 | 1.7 | 2.7 |
| 26 | 17.3 | 2.8 | 1.7 | 1.1 | 4.0 | 0.8 | 1.2 | 5.7 |
| 37 | 17.5 | 4.7 | 0.5 | 1.0 | 5.2 | 1.7 | 0.9 | 3.5 |
| 43 | 20.1 | 2.1 | 4.4 | 2.7 | 2.7 | 2.3 | 1.7 | 4.1 |
| 48 | 20.1 | 1.1 | 1.8 | 0.8 | 1.1 | 1.7 | 1.3 | 12.3 |
| 44 | 21.2 | 2.7 | 0.8 | 0.5 | 0.5 | 0.5 | 1.5 | 14.8 |
| 29 | 22.4 | 2.4 | 5.2 | 0.6 | 4.7 | 3.1 | 1.0 | 5.4 |
| 13 | 23.5 | 5.4 | 2.0 | 0.0 | 7.5 | 2.1 | 1.9 | 4.6 |
| 24 | 24.5 | 5.1 | 8.6 | 0.5 | 3.1 | 1.4 | 2.4 | 3.4 |
| 35 | 25.8 | 5.8 | 4.9 | 1.2 | 5.0 | 2.8 | 0.6 | 5.5 |
| 16 | 26.4 | 4.4 | 4.2 | 2.2 | 2.5 | 2.8 | 3.0 | 7.2 |
| 27 | 29.3 | 3.2 | 10.8 | 0.0 | 4.0 | 1.7 | 0.8 | 8.8 |
| 31 | 29.3 | 5.6 | 4.1 | 1.8 | 1.9 | 7.7 | 0.8 | 7.5 |
| 36 | 31.3 | 7.0 | 5.2 | 3.7 | 2.3 | 6.8 | 2.4 | 3.8 |
| 20 | 34.7 | 7.7 | 10.8 | 2.0 | 5.5 | 4.6 | 0.2 | 3.8 |
| 30 | 35.2 | 2.7 | 12.5 | 0.2 | 3.2 | 2.7 | 1.9 | 11.9 |
| 7 | 35.7 | 7.4 | 6.6 | 1.0 | 2.5 | 1.5 | 6.7 | 10.0 |
| 28 | 37.4 | 11.3 | 3.3 | 1.0 | 5.4 | 3.1 | 4.5 | 8.8 |
| 10 | 37.5 | 4.6 | 7.2 | 3.0 | 3.6 | 5.6 | 6.7 | 6.8 |
| 34 | 37.7 | 4.1 | 4.9 | 7.9 | 8.0 | 6.2 | 2.3 | 4.2 |
| 9 | 38.2 | 2.6 | 4.7 | 0.2 | 11.0 | 8.3 | 3.7 | 7.7 |
| 50 | 38.7 | 8.2 | 8.3 | 2.7 | 7.3 | 1.3 | 4.2 | 6.8 |
| 33 | 39.2 | 2.8 | 12.3 | 3.0 | 6.6 | 3.3 | 3.5 | 7.7 |
| 19 | 40.4 | 10.4 | 4.5 | 2.7 | 13.7 | 3.8 | 0.0 | 5.2 |
| 38 | 40.7 | 5.0 | 4.8 | 4.2 | 6.2 | 7.0 | 2.9 | 10.6 |
| 42 | 44.8 | 7.0 | 7.9 | 2.3 | 8.2 | 5.7 | 0.5 | 13.3 |
| 11 | 45.6 | 11.3 | 7.3 | 0.8 | 7.7 | 6.9 | 5.2 | 6.4 |
| 8 | 52.6 | 9.6 | 4.6 | 2.5 | 8.5 | 7.5 | 6.1 | 13.8 |
| 1 | 53.7 | 14.0 | 8.2 | 0.0 | 5.8 | 16.7 | 4.3 | 4.7 |
| 15 | 57.3 | 9.2 | 5.1 | 4.7 | 15.9 | 4.6 | 3.9 | 13.9 |
| 21 | 67.4 | 11.1 | 12.5 | 1.8 | 13.9 | 6.3 | 8.8 | 13.0 |
| 14 | 71.3 | 12.8 | 0.2 | 0.0 | 41.0 | 1.3 | 2.7 | 13.3 |
| 3 | 72.0 | 18.5 | 7.7 | 1.8 | 11.7 | 14.8 | 1.5 | 16.2 |
| 2 | 80.5 | 6.6 | 15.3 | 0.2 | 11.8 | 4.2 | 25.9 | 16.4 |
| 4 | 86.5 | 13.6 | 9.2 | 0.2 | 19.7 | 16.8 | 10.8 | 16.3 |
| 12 | 87.1 | 17.9 | 6.7 | 0.5 | 22.3 | 20.3 | 8.9 | 10.4 |
| 40 | 92.3 | 15.3 | 5.3 | 7.5 | 8.8 | 6.2 | 21.0 | 28.2 |

ID, patient number; TOTAL, total grid variance.

Table 6.38: Summary of element variances in order of variability, epilepsy patients with grid data on 4 occasions (n=43).

| Variable | Mean[a] | SD | Range |
|---|---|---|---|
| LIKE | 1.65 | 1.83 | 0.00- 7.92 |
| BEST | 3.71 | 5.15 | 0.00-25.92 |
| FRIEND | 4.78 | 4.64 | 0.00-20.25 |
| BEFORE | 5.67 | 3.63 | 0.25-15.25 |
| NOW | 6.45 | 4.73 | 0.92-18.50 |
| EXPECT | 7.10 | 7.32 | 0.50-41.00 |
| WORST | 8.48 | 5.17 | 2.75-28.17 |
| TOTAL | 37.85 | 22.32 | 7.58-92.33 |

[a] Low mean indicates low variability; TOTAL, total grid variance

differences are evident in degree of variability (ie. some patients are more variable than others), there is a fair degree of concordance in ranking the variability of the elements (ie. some elements are more variable than others and this variability in similar across patients). There thus appears to be some agreement among patients as to which elements are stable and which are not.

In summary, LIKE appears to be the most stably rated element. This is to be expected, partly due to the rating system used (No problem - It could not be worse). It seems likely that the majority of people would consistently use the lower ends of this scale when identifying the situation they would like to see themselves in. BEST/FRIEND/BEFORE are next in line in relation to stability. This fits in with the hypothesis that concrete situations are likely to be more stable than hypothetical ones. NOW shows quite high variability (in relation to the other elements). This is not unexpected as it is likely that people's situation will change over time and thus their ratings would alter accordingly. What is a problem now, may not be in 6 months time. The highest variability was seen for the element WORST (the worst life imaginable). Patients did seem to have problems imagining the worst life imaginable or were reluctant to choose an actual person. Often fairly vague concepts were thought about, for example, people in the Third World, tramps/homeless people. This seems to have been reflected in the high variation in ratings seen for this element. This finding raised doubts as to the usefulness of this element in the RG structure.

### 6.3.b.ii **Construct stability**

Details of individual patient construct variances are listed in Table 6.39 and a summary of these data is given in Table 6.40. A wide between-subject variability was seen, with construct variance values ranging from 0.0 to 15.0. However, the actual means were reasonably low (3.03-4.39), particularly in relation to the maximum possible variance for any one construct which is 37.3.

As hypothesised, no agreement was seen among patients as to the ordering of construct variability (Kendalls W=0.032,

$X^2$=12.28, df=9, p=0.198). This is reassuring as all patients had different constructs and if concordance among patients had been seen this would have been worrying!!.

Table 6.39: Construct variances by individual patient (43 epilepsy cases), listed in increasing order of total grid variability.

| | | CONSTRUCTS | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| ID | TOT | C1 | C2 | C3 | C4 | C5 | C6 | C7 | C8 | C9 | C10 |
| 49 | 7.6 | 0.6 | 0.6 | 1.7 | 0.3 | 0.9 | 0.9 | 0.3 | 1.3 | 0.0 | 0.9 |
| 32 | 8.4 | 0.3 | 0.3 | 0.5 | 1.2 | 1.9 | 0.3 | 1.4 | 0.5 | 1.6 | 0.3 |
| 5 | 11.9 | 1.0 | 1.0 | 1.3 | 0.8 | 2.3 | 1.3 | 1.4 | 0.8 | 0.2 | 1.7 |
| 39 | 15.1 | 2.0 | 0.8 | 0.6 | 2.2 | 1.2 | 0.6 | 1.9 | 1.0 | 2.2 | 2.6 |
| 46 | 15.8 | 1.8 | 0.2 | 2.2 | 2.5 | 1.4 | 0.2 | 1.9 | 2.1 | 1.5 | 1.9 |
| 47 | 16.3 | 0.2 | 0.2 | 0.6 | 1.4 | 1.4 | 0.3 | 3.3 | 0.6 | 5.1 | 3.1 |
| 25 | 16.9 | 1.7 | 2.7 | 0.8 | 1.0 | 1.8 | 1.7 | 1.7 | 2.2 | 1.8 | 1.6 |
| 26 | 17.3 | 0.5 | 1.0 | 1.7 | 2.5 | 2.2 | 2.5 | 2.5 | 1.7 | 1.7 | 1.0 |
| 37 | 17.5 | 2.1 | 2.2 | 2.7 | 0.9 | 2.9 | 1.3 | 1.3 | 1.4 | 1.2 | 1.5 |
| 43 | 20.1 | 2.5 | 2.9 | 4.5 | 3.1 | 1.7 | 0.3 | 0.9 | 1.8 | 1.6 | 0.8 |
| 48 | 20.1 | 3.7 | 0.8 | 2.2 | 1.6 | 3.2 | 0.9 | 3.4 | 1.3 | 1.5 | 1.5 |
| 44 | 21.2 | 3.0 | 1.7 | 4.2 | 3.0 | 0.0 | 1.0 | 1.3 | 2.2 | 2.7 | 2.0 |
| 29 | 22.4 | 0.3 | 2.1 | 0.8 | 0.8 | 1.7 | 1.3 | 3.1 | 9.2 | 2.9 | 0.2 |
| 13 | 23.5 | 0.2 | 6.1 | 3.7 | 1.0 | 2.2 | 1.7 | 2.7 | 1.3 | 2.8 | 1.8 |
| 24 | 24.5 | 1.2 | 1.4 | 2.1 | 2.6 | 3.4 | 3.3 | 1.7 | 3.4 | 4.0 | 1.4 |
| 35 | 25.8 | 1.9 | 2.3 | 4.8 | 1.8 | 2.7 | 2.3 | 0.0 | 1.4 | 3.4 | 5.1 |
| 16 | 26.4 | 0.6 | 2.8 | 2.7 | 1.9 | 1.4 | 2.4 | 2.2 | 1.6 | 4.9 | 5.7 |
| 27 | 29.3 | 1.9 | 3.1 | 1.4 | 3.4 | 3.2 | 3.7 | 3.0 | 1.3 | 2.9 | 5.4 |
| 31 | 29.3 | 2.8 | 11.8 | 1.8 | 2.6 | 0.2 | 0.3 | 2.7 | 3.3 | 2.2 | 1.6 |
| 36 | 31.3 | 1.8 | 3.0 | 3.1 | 1.8 | 2.6 | 1.9 | 10.3 | 1.7 | 2.9 | 2.2 |
| 20 | 34.7 | 2.7 | 2.8 | 5.8 | 4.0 | 2.8 | 6.1 | 3.1 | 2.9 | 4.0 | 0.5 |
| 30 | 35.2 | 3.8 | 3.8 | 3.0 | 3.5 | 2.2 | 2.5 | 2.4 | 6.0 | 5.0 | 2.8 |
| 7 | 35.7 | 1.0 | 7.5 | 1.0 | 0.2 | 2.0 | 0.0 | 3.2 | 4.4 | 5.9 | 10.4 |
| 28 | 37.4 | 2.8 | 4.2 | 6.1 | 2.2 | 3.7 | 4.8 | 2.2 | 2.2 | 1.8 | 7.3 |
| 10 | 37.5 | 4.0 | 3.9 | 2.9 | 4.6 | 4.7 | 3.7 | 4.8 | 2.4 | 3.1 | 3.4 |
| 34 | 37.7 | 2.6 | 4.7 | 1.8 | 1.0 | 2.7 | 4.5 | 1.7 | 5.7 | 9.3 | 3.7 |
| 9 | 38.2 | 7.2 | 4.0 | 2.8 | 2.6 | 7.4 | 6.9 | 0.0 | 0.5 | 1.8 | 5.0 |
| 50 | 38.7 | 2.1 | 4.5 | 2.8 | 7.4 | 4.1 | 3.1 | 3.0 | 3.2 | 6.7 | 1.7 |
| 33 | 39.2 | 4.8 | 1.9 | 1.5 | 4.3 | 6.4 | 2.4 | 6.6 | 5.4 | 3.9 | 1.8 |
| 19 | 40.4 | 3.0 | 1.3 | 3.5 | 3.5 | 5.2 | 5.7 | 9.2 | 3.6 | 1.5 | 4.0 |
| 38 | 40.7 | 5.1 | 6.0 | 3.9 | 3.4 | 3.0 | 3.0 | 2.2 | 5.7 | 3.5 | 4.9 |
| 42 | 44.8 | 3.3 | 1.5 | 5.0 | 4.2 | 5.1 | 6.1 | 3.5 | 6.8 | 5.5 | 3.8 |
| 11 | 45.6 | 2.2 | 4.5 | 1.3 | 3.0 | 7.7 | 3.0 | 8.7 | 5.0 | 6.1 | 4.1 |
| 8 | 52.6 | 5.9 | 16.2 | 7.7 | 1.0 | 6.4 | 3.9 | 1.6 | 2.6 | 5.0 | 2.2 |
| 1 | 53.7 | 4.8 | 5.8 | 4.2 | 3.2 | 1.3 | 10.8 | 6.9 | 5.4 | 9.2 | 2.2 |
| 15 | 57.3 | 4.2 | 8.8 | 4.7 | 2.5 | 4.2 | 5.8 | 11.2 | 5.3 | 5.1 | 5.4 |
| 21 | 67.4 | 4.2 | 7.2 | 8.0 | 5.7 | 10.7 | 4.8 | 9.3 | 7.9 | 4.4 | 5.2 |
| 14 | 71.3 | 4.5 | 4.5 | 7.2 | 7.2 | 9.5 | 4.2 | 3.7 | 9.0 | 15.2 | 6.2 |
| 3 | 72.0 | 2.2 | 8.7 | 9.8 | 7.7 | 6.2 | 7.7 | 5.5 | 7.1 | 10.4 | 6.8 |
| 2 | 80.5 | 10.4 | 7.0 | 9.2 | 7.4 | 8.3 | 8.7 | 4.5 | 10.4 | 4.8 | 9.8 |
| 4 | 86.5 | 2.9 | 2.1 | 7.8 | 10.6 | 6.3 | 12.8 | 10.1 | 9.7 | 9.9 | 14.3 |
| 12 | 87.1 | 7.7 | 9.7 | 9.8 | 9.1 | 3.2 | 13.8 | 5.5 | 9.1 | 9.1 | 10.2 |
| 40 | 92.3 | 8.8 | 11.4 | 10.0 | 9.2 | 12.8 | 9.8 | 12.8 | 5.7 | 10.3 | 3.7 |

ID, patient number; TOT, total grid variance; C1, construct 1; C2, construct 2 ..... C10, construct 10.

Note: Constructs 1 and 2 = physical domain
Constructs 3 and 4 = cognitive domain
Constructs 5 and 6 = emotional domain
Constructs 7 and 8 = social domain
Constructs 9 and 10 = economic/employment domain

Table 6.40: Summary of construct variances, epilepsy patients (n=43)

| Variable | Mean[a] | SD | Range |
|---|---|---|---|
| CONSTRUCT 1 | 3.03 | 2.31 | 0.25-10.42 |
| CONSTRUCT 2 | 4.16 | 3.54 | 0.25-16.17 |
| CONSTRUCT 3 | 3.80 | 2.78 | 0.50-10.00 |
| CONSTRUCT 4 | 3.34 | 2.58 | 0.25-10.58 |
| CONSTRUCT 5 | 3.78 | 2.72 | 0.00-10.83 |
| CONSTRUCT 6 | 3.78 | 3.41 | 0.00-13.83 |
| CONSTRUCT 7 | 3.92 | 3.23 | 0.00-12.75 |
| CONSTRUCT 8 | 3.87 | 2.86 | 0.50-10.42 |
| CONSTRUCT 9 | 4.39 | 3.24 | 0.00-15.00 |
| CONSTRUCT 10 | 3.76 | 3.06 | 0.25-14.25 |
| TOTAL | 37.85 | 22.32 | 7.58-92.33 |

[a] Low mean indicates low variability
SD, standard deviation; TOTAL, total grid variance
Note: Constructs 1 and 2 = physical domain
Constructs 3 and 4 = cognitive domain
Constructs 5 and 6 = emotional domain
Constructs 7 and 8 = social domain
Constructs 9 and 10 = economic/employment domain

# CHAPTER 6

# RESULTS

## 6.4. PSYCHOMETRIC PROPERTIES OF INDEPENDENT MEASURES USED AS VALIDATORS FOR QOLAS

## 6.4. PSYCHOMETRIC PROPERTIES OF QUESTIONNAIRE MEASURES

Full details of frequency measures (mean, SD, median, range) for each of the independent questionnaires employed in the study (GRS, SIP, MACL and LES) on each occasion can be found in Appendices 28 - 31.

### 6.4.a Influence of age and IQ

#### 6.4.a.i **Global rating scale**

No significant correlations between GRS ratings and age were seen (See Table 6.41). A number of significant correlations, however, were seen between measures of intellectual level and responses to the global rating scale. GRS1 (Life in general) showed moderate and signficant correlations with both FSIQ and PIQ (FSIQ, $r=.41$, $p<.05$; PIQ, $r=.51$, $p<.01$). GRS2 (Physical ability) correlated significantly with PIQ only ($r=.44$, $p<.04$). GRS5 (Social life), GRS6 (Employment) and GRS7 (Financial status) correlated significantly with both FSIQ and PIQ (See Table 6.41 for details). No significant correlations between GRS ratings and verbal IQ scores were seen. Full details of all correlations are given in Table 6.41.

#### 6.4.a.ii **Sickness Impact Profile**

No significant correlations between SIP sub-scale scores and age or intellectual level were seen with coefficients (Spearmans rho) ranging from 0.01 to 0.35. Full details of all correlations are given in Table 6.42.

#### 6.4.a.iii **Mood Adjective Checklist**

Low correlations were seen between all MACL sub-scales (Anxiety, Fatigue, Hostility, Vigour and Depression) and age. A modest, negative correlation was seen between the Vigour sub-scale and full-scale IQ ($r=-.36$, $p<.03$). All other correlations with IQ scores were low and non-significant, ranging from 0.0 to 0.28 (see Table 6.43).

Table 6.41: Correlations[a] between age, intellectual level and GRS scores; session 4 data.

| | AGE (n=25) | | FSIQ (n=23) | | PIQ (n=23) | | VIQ (n=23) | |
|---|---|---|---|---|---|---|---|---|
| | r | p | r | p | r | p | r | p |
| GRS1 | .20 | .34 | .41 | .05 | .51 | .01 | .24 | .26 |
| GRS2 | -.14 | .50 | .26 | .24 | .44 | .04 | .00 | 1.0 |
| GRS3 | .01 | .95 | .35 | .10 | .33 | .13 | .41 | .06 |
| GRS4 | .28 | .17 | .22 | .31 | .37 | .09 | .11 | .63 |
| GRS5 | .25 | .23 | .45 | .03 | .47 | .02 | .32 | .14 |
| GRS6 | .04 | .85 | .54 | .01 | .55 | .01 | .35 | .10 |
| GRS7 | .16 | .45 | .52 | .01 | .50 | .01 | .41 | .06 |

[a] Pearsons r

GRS1, life in general; GRS2, physical ability; GRS3, cognitive ability; GRS4, emotional state; GRS5, social life/relationships; GRS6, employment/daytime activity; GRS7, finances.

Table 6.42: Correlations[a] of age and IQ scores with SIP sub-scales; occasion 4 data, all epilepsy patients.

| | AGE (n=39) | | FSIQ (n=36) | | VIQ (n=36) | | PIQ (n=36) | |
|---|---|---|---|---|---|---|---|---|
| | r | p | r | p | r | p | r | p |
| AMB | .19 | .24 | -.04 | .83 | -.06 | .74 | - .01 | .94 |
| MOB | .15 | .35 | .03 | .88 | .04 | .83 | .11 | .52 |
| BCM | .10 | .56 | .22 | .19 | .08 | .65 | .35 | .04 |
| SI | .05 | .76 | .02 | .92 | -.02 | .91 | .05 | .76 |
| COM | .007 | .97 | -.08 | .63 | -.13 | .46 | -.03 | .84 |
| AB | .11 | .51 | .12 | .49 | .02 | .92 | .19 | .28 |
| EM | -.04 | .83 | .11 | .52 | .09 | .59 | .14 | .43 |
| SR | .23 | .16 | .16 | .34 | .10 | .56 | .24 | .16 |
| EAT | -.17 | .30 | -.09 | .58 | .04 | .80 | -.11 | .52 |
| WORK | -.08 | .62 | .12 | .50 | .03 | .84 | .02 | .89 |
| HM | -.04 | .80 | .17 | .31 | .08 | .66 | .25 | .14 |
| REC | .07 | .68 | .10 | .58 | .12 | .48 | .13 | .45 |
| PHYS | .21 | .19 | .17 | .32 | .08 | .63 | .24 | .15 |
| SOC | .12 | .48 | .10 | .57 | -.02 | .89 | .18 | .30 |
| TOTAL | .20 | .22 | .18 | .30 | .07 | .69 | .24 | .16 |

[a] Spearman rank order correlation coefficients

Table 6.43: Correlations[a] of MACL scores with age and IQ measures; epilepsy patients, session 4 data

| MACL scale | AGE (n=43) | | FSIQ (n=39) | | PIQ (n=39) | | VIQ (n=39) | |
|---|---|---|---|---|---|---|---|---|
| | r | p | r | p | r | p | r | p |
| Anxiety | -.14 | .35 | .03 | .86 | .11 | .51 | .18 | .27 |
| Fatigue | .04 | .78 | .02 | .91 | .13 | .42 | .08 | .61 |
| Hostility | -.04 | .81 | .00 | 1.0 | .22 | .18 | .08 | .61 |
| Vigour | .10 | .95 | -.36 | .03 | -.26 | .10 | -.28 | .09 |
| Depression | -.10 | .53 | .08 | .61 | .23 | .15 | .12 | .48 |

[a] Pearsons r

### 6.4.a.iv **Life Events Scale**

LES positive scores showed significant, negative correlations with age (Positive score, rho=-.40, p<.007). Negative events, total events and the discrepancy score (positive minus negative) showed no relationship to the age of the subject. No correlation with intellectual level was seen for any of the life event scores. Full details of age and IQ correlations are given in Table 6.44.

## 6.4.b <u>Influence of gender</u>

### 6.4.b.i **All epilepsy patient data**

MACL anxiety scores show a small, but significant gender difference (F=5.23, p<.03). No significant gender effects were seen for any of the other MACL sub-scales or the other questionnaires employed in this study (GRS, SIP, LES). Full details of the results of these analyses are given in Appendices 32 - 35.

### 6.4.b.ii **Matched group (n=18)**

In this more detailed analysis of the effect of gender, none of the measures assessed (GRS, SIP, MACL, LES) showed any significant discrepancy based upon the sex of subjects.

Table 6.44: Correlations[a] of age and IQ with LES scores; epilepsy patients, session 4 data.

| | AGE (n=44) | | FSIQ (n=40) | | PIQ (n=40) | | VIQ (n=40) | |
|---|---|---|---|---|---|---|---|---|
| | r | p | r | p | r | p | r | p |
| LESP | -.40 | .007 | .14 | .39 | .14 | .40 | .26 | .11 |
| LESN | -.18 | .24 | .13 | .43 | .18 | .27 | .01 | .97 |
| LEST | -.34 | .02 | .21 | .02 | .21 | .19 | .16 | .33 |
| LESD | -.13 | .39 | .12 | .47 | .008 | .96 | .25 | .13 |

[a] Spearmans rho

LESP, positive life events score; LESN, negative life events score; LEST, total life events score; LESD, life events discrepancy score.

### 6.4.c Temporal stability

#### 6.4.c.i Global Rating Scale.

Full details of the test retest coefficients for all GRS ratings are shown in Table 6.45, with summaries of these data by individual measure and time interval given in Tables 6.46 and 6.47 respectively. Overall, the GRS shows a moderate degree of temporal stability (mean correlation (averaged over all GRS scales and all session pairings)=0.53, range=0.17 - 0.84) (Table 6.46). Variation between GRS ratings in terms of overall temporal stability were seen with the ratings for satisfaction with social life (GRS5) showing the highest temporal stability (mean correlation, averaged across sessions=0.65, range=0.54-0.75) and the ratings for satisfaction with life in general (GRS1) showing the lowest stability over time (mean correlation=0.38, range=0.17-0.73) (See Table 6.46).

Little difference was seen between the various time intervals with regard to mean test-retest correlations (see Table 6.47). All time intervals (ranging from 1 to 6 months) demonstrated moderate test-retest correlations mean values ranging from 0.42 (6 months) to 0.61 (2 months).

#### 6.4.c.ii Sickness Impact Profile.

Data relating to the temporal stability of SIP scores (both dimension and category) are shown in Tables 6.48 to 6.52. Many significant correlations across session pairings were seen for all SIP dimension (Table 6.48) and category (Table 6.49) scores, indicating good overall temporal stability.

Table 6.45: GRS: temporal stability coefficients, epilepsy group (n=22)

| Session pairing | Time interval | | GRS rating | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| | | | GRS1 | GRS2 | GRS3 | GRS4 | GRS5 | GRS6 | GRS7 |
| S1 v S2 | 1 month | r | .18 | .47 | .60 | .51 | .75 | .71 | .73 |
| | | p | .42 | .03 | .003 | .02 | .000 | .00 | .000 |
| S2 v S3 | 2 months | r | .73 | .60 | .72 | .66 | .60 | .32 | .65 |
| | | p | .000 | .003 | .000 | .001 | .003 | .15 | .001 |
| S1 v S3 | 3 months | r | .17 | .51 | .64 | .67 | .56 | .48 | .51 |
| | | p | .44 | .02 | .001 | .001 | .007 | .02 | .02 |
| S3 v S4 | 3 months | r | .52 | .56 | .57 | .49 | .71 | .84 | .38 |
| | | p | .01 | .007 | .006 | .02 | .000 | .000 | .08 |
| S2 v S4 | 5 months | r | .49 | .42 | .49 | .20 | .75 | .54 | .62 |
| | | p | .02 | .05 | .02 | .37 | .000 | .01 | .002 |
| S1 v S4 | 6 months | r | .19 | .19 | .62 | .46 | .54 | .40 | .55 |
| | | p | .40 | .40 | .002 | .03 | .009 | .06 | .009 |

GRS1, life in general; GRS2, physical functioning; GRS3, cognitive ability; GRS4, emotional state; GRS5, social life; GRS6, employment; GRS7, finances.

Table 6.46: Summary of mean test retest correlations[a] for GRS, averaged across all session pairings (epilepsy patients, n=22).

| | Mean[b] | Range |
|---|---|---|
| GRS5 (Social) | 0.65 | 0.54-0.75 |
| GRS3 (Cognitive) | 0.61 | 0.49-0.72 |
| GRS7 (Finances) | 0.57 | 0.38-0.73 |
| GRS6 (Employment) | 0.55 | 0.32-0.84 |
| GRS4 (Emotional) | 0.50 | 0.20-0.67 |
| GRS2 (Physical) | 0.46 | 0.19-0.60 |
| GRS1 (Overall QOL) | 0.38 | 0.17-0.73 |
| All ratings | 0.53 | 0.17-0.84 |

[a] Pearson product moment correlations
[b] Higher correlation indicates greater temporal stability

Table 6.47: GRS: mean test retest correlations, averaged across all ratings (all epilepsy patients, n=22): Comparison of stability over varying time intervals.

| Session pairing | Time interval | Mean[a] | Range |
|---|---|---|---|
| S1 v S2 | 1 month | 0.56 | 0.18-0.75 |
| S2 v S3 | 2 months | 0.61 | 0.32-0.73 |
| S1 v S3 | 3 months | 0.51 | 0.17-0.67 |
| S3 v S4 | 3 months | 0.43 | 0.22-0.70 |
| S2 v S4 | 5 months | 0.58 | 0.38-0.84 |
| S1 v S4 | 6 months | 0.42 | 0.19-0.62 |
| All ratings | | 0.53 | 0.17-0.84 |

Tables 6.50 and 6.51 summarise the mean test-retest correlations for each SIP dimension (12 dimensions) and category scores (3 composite measures). For the twelve dimension scores it can be seen that while the overall mean correlation is moderate (r=0.58, see Table 6.50), there is wide variation between the dimensions regarding their temporal stability. Correlation coefficients vary from 0.32 (Household Management) to 0.82 (Emotions).

The three category scores (Physical, Psychosocial and Total SIP scores) all showed good temporal stability with test-retest correlations ranging from 0.61 to 0.72 (see Table 6.51). The psychosocial category score, however, appears to show the greatest variation with individual test-retest correlations (separate session pairings) ranging from 0.31 to 0.83 (Table 6.51).

Little difference is apparent between the various time intervals for either dimension or category scores, suggesting that the SIP is stable over periods of up to 6 months (see Table 6.52).

Table 6.48: Inter-session correlations[a] for SIP dimension scores (Study 2 patients, n=23).

| | | | SIP Dimension | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | Int | | AMB | MOB | BCM | SI | COM | AB | EM | SR | EAT | WRK | HM | REC |
| S1vS2 | 1 | r | .70 | .41 | .83 | .78 | .65 | .62 | .87 | .73 | .38 | .92 | .29 | .72 |
| | | p | .000 | .05 | .000 | .000 | .001 | .002 | .000 | .000 | .07 | .000 | .17 | .000 |
| S2vS3 | 2 | r | .62 | .51 | .88 | .89 | .47 | .75 | .79 | .72 | .26 | .90 | .21 | -.03 |
| | | p | .002 | .01 | .000 | .000 | .03 | .000 | .000 | .000 | .22 | .000 | .35 | .89 |
| S1vS3 | 3 | r | .63 | .75 | .65 | .84 | .45 | .78 | .77 | .78 | .35 | .84 | .79 | .51 |
| | | p | .001 | .000 | .001 | .000 | .03 | .000 | .000 | .000 | .10 | .000 | .000 | .01 |
| S3vS4 | 3 | r | .78 | .75 | .59 | .28 | .42 | .37 | .71 | .64 | .64 | .68 | .37 | .77 |
| | | p | .000 | .000 | .003 | .20 | .05 | .09 | .000 | .001 | .001 | .000 | .08 | .000 |
| S2vS4 | 5 | r | .74 | .46 | .83 | .18 | .52 | .47 | .88 | .40 | .52 | .71 | -.07 | .28 |
| | | p | .000 | .03 | .000 | .41 | .01 | .02 | .000 | .06 | .01 | .000 | .75 | .19 |
| S1vS4 | 6 | r | .59 | .57 | .86 | .37 | .28 | .33 | .89 | .59 | .54 | .59 | .31 | .58 |
| | | p | .003 | .004 | .000 | .08 | .20 | .13 | .000 | .003 | .007 | .003 | .15 | .004 |

[a] Spearmans rank order correlation coefficients.

S1, Baseline; S2, 1 month; S3, 3 months; S4, 6 months; Int, time interval in months; AMB=Ambulation; MOB=Mobility; BCM=Bodycare and movement; SI=Social interaction; COM=Communication; AB=Alertness behaviour; EM=Emotional; SR=Sleep and rest; EAT=Eating; WRK=Work; HM=Household management; REC=recreation.

Table 6.49: Inter-session correlations[a] for SIP category scores; Study 2 patients, n=23).

| | | | SIP Composite Score | | |
|---|---|---|---|---|---|
| | Interval | | PHYS | SOC | SIP |
| S1vS2 | 1 month | r | .80 | .83 | .86 |
| | | p | .000 | .000 | .000 |
| S2vS3 | 2 months | r | .75 | .82 | .84 |
| | | p | .000 | .000 | .000 |
| S1vS3 | 3 months | r | .69 | .74 | .74 |
| | | p | .000 | .000 | .000 |
| S3vS4 | 3 months | r | .64 | .31 | .60 |
| | | p | .001 | .15 | .002 |
| S2vS4 | 5 months | r | .77 | .50 | .67 |
| | | p | .000 | .02 | .000 |
| S1vS4 | 6 months | r | .79 | .45 | .62 |
| | | p | .000 | .03 | .002 |

[a] Spearmans rho
PHYS=Physical score; SOC=Psychosocial score; SIP=Total score.

Table 6.50: SIP: mean inter-session correlations, averaged across all session pairings; epilepsy patients, n= 23. Comparison of stability of individual dimensions.

| Scale | Mean[a] | Range |
|---|---|---|
| AMB | 0.68 | 0.59 - 0.78 |
| MOB | 0.58 | 0.41 - 0.75 |
| BCM | 0.77 | 0.59 - 0.88 |
| SI | 0.56 | 0.18 - 0.89 |
| COM | 0.47 | 0.28 - 0.65 |
| AB | 0.55 | 0.33 - 0.78 |
| EM | 0.82 | 0.71 - 0.89 |
| SR | 0.63 | 0.40 - 0.78 |
| EAT | 0.45 | 0.26 - 0.64 |
| WRK | 0.77 | 0.59 - 0.92 |
| HM | 0.32 | -.07 - 0.79 |
| REC | 0.47 | -.03 - 0.77 |
| All ratings | 0.58 | -.03 - 0.92 |

Spearmans rho

Table 6.51: SIP: mean inter-session correlations, averaged across all session pairings; epilepsy patients, n=23. Comparison of stability of SIP category scores.

| Scale | Mean[a] | Range |
|---|---|---|
| PHYSICAL | 0.74 | 0.64 - 0.80 |
| PSYCHOSOCIAL | 0.61 | 0.31 - 0.83 |
| SIP TOTAL | 0.72 | 0.60 - 0.86 |
| All ratings | 0.69 | 0.31 - 0.86 |

Table 6.52: SIP: mean test retest correlations, averaged across sub-scales (epilepsy patients, n=23): Comparison of stability over time intervals.

| | | Averaged across 12 SIP dimensions | | Averaged across 3 SIP category scales | |
|---|---|---|---|---|---|
| Session pairing | Time interval | Mean | Range | Mean | Range |
| S1 v S2 | 1 month | 0.66 | 0.29 - 0.92 | 0.83 | 0.83 - 0.86 |
| S2 v S3 | 2 months | 0.58 | -.03 - 0.90 | 0.80 | 0.75 - 0.84 |
| S1 v S3 | 3 months | 0.68 | 0.35 - 0.84 | 0.72 | 0.64 - 0.74 |
| S3 v S4 | 3 months | 0.58 | 0.28 - 0.78 | 0.52 | 0.31 - 0.64 |
| S2 v S4 | 5 months | 0.45 | -.07 - 0.88 | 0.65 | 0.50 - 0.77 |
| S1 v S4 | 6 months | 0.54 | 0.31 - 0.89 | 0.62 | 0.45 - 0.79 |
| All ratings | | 0.58 | -.03 - 0.92 | 0.69 | 0.31 - 0.86 |

12 SIP dimensions=AMB, MOB, BCM, SI, COM, AB, EM, SR, WORK, HM, REC, EAT.
3 SIP composite scores=PHYS, SOC, SIP.

6.4.c.iii **Mood Adjective Checklist.**

Full details of the inter-session correlations for all MACL sub-scales are given in Table 6.53. Moderate to high correlations were seen for all scales and all session pairings (mean correlation averaged across all scales and all session pairings= 0.63; range=0.23 - 0.92) (Table 6.54). A high correlation was seen for all individual sub-scales with coefficients ranging from 0.51 (Vigour) to 0.70 (Anxiety). Mean correlations for the differing time intervals (averaged across all sub-scales) were remarkably similar, ranging from 0.56 (S2 v S4, 5 month test-retest interval) to 0.71 (S3 v S4, 3 month test-retest interval) (see Table 6.55). This suggests that the MACL has good temporal stability over intervals of up to 6 months.

Table 6.53: MACL: temporal stability coefficients, epilepsy group (n=24)

| Session pairing | Time interval | | MACL Sub-Scale | | | | |
|---|---|---|---|---|---|---|---|
| | | | Anx | Fat | Host | Vig | Dep |
| S1 v S2 | 1 month | r | .80 | .63 | .48 | .53 | .52 |
| | | p | .000 | .000 | .02 | .007 | .009 |
| S2 v S3 | 2 months | r | .92 | .70 | .71 | .23 | .47 |
| | | p | .000 | .000 | .000 | .28 | .02 |
| S1 v S3 | 3 months | r | .69 | .66 | .83 | .45 | .72 |
| | | p | .000 | .000 | .000 | .03 | .000 |
| S3 v S4 | 3 months | r | .61 | .82 | .74 | .70 | .67 |
| | | p | .001 | .000 | .000 | .000 | .000 |
| S2 v S4 | 5 months | r | .59 | .73 | .49 | .53 | .44 |
| | | p | .002 | .000 | .02 | .008 | .03 |
| S1 v S4 | 6 months | r | .58 | .61 | .79 | .59 | .60 |
| | | p | .003 | .002 | .000 | .003 | .002 |

S1, Baseline; S2, 1 month; S3, 3 months; S4, 6 months.
r, Pearsons correlation coefficient; p, 2-tailed significance;
Anx, anxiety; Fat, fatigue; Host, hostility; Vig, vigour; Dep, depression.

Table 6.54: MACL: mean test retest correlations, averaged across all session pairings (epilepsy patients, n=24): Comparison of stability of individual sub-scales.

| Sub-scale | Mean[a] | Range |
|---|---|---|
| Anxiety | 0.70 | 0.58-0.92 |
| Fatigue | 0.69 | 0.61-0.82 |
| Hostility | 0.67 | 0.48-0.83 |
| Vigour | 0.51 | 0.23-0.70 |
| Depression | 0.57 | 0.44-0.72 |
| All ratings | 0.63 | 0.23-0.92 |

Table 6.55: MACL: mean test retest correlations, averaged across all sub-scales (epilepsy patients, n=24): Comparison of stability over varying time intervals.

| Session pairing | Time interval | Mean[a] | Range |
|---|---|---|---|
| S1 v S2 | 1 month | 0.59 | 0.48-0.80 |
| S2 v S3 | 2 months | 0.61 | 0.23-0.92 |
| S1 v S3 | 3 months | 0.67 | 0.45-0.83 |
| S3 v S4 | 3 months | 0.71 | 0.61-0.82 |
| S2 v S4 | 5 months | 0.56 | 0.44-0.73 |
| S1 v S4 | 6 months | 0.63 | 0.58-0.79 |
| All ratings | | 0.63 | 0.23-0.92 |

### 6.4.d Validity

The hypothesised multi-trait, multi-method matrix for the independent measures is shown in Table 6.56.

#### 6.4.d.i Global rating scale

GRS1 (satisfaction with life in general) showed a low correlation with the other independent measure of overall QOL (SIP total score, r=0.24). This scale correlated more highly with measures of cognitive status (GRS3, r=0.50; SIP-AB, r=0.36), social functioning (GRS5, r=0.38) and physical ability (SIP-PHYS, r=0.37).

GRS2 (satisfaction with physical abilities) correlated highly with the composite physical SIP score (r=.71, p<.001) (Table 6.59). This is in line with the expected hypothesis and suggests that both these scales are valid indicators of physical functioning.

GRS3, a measure of satisfaction with cognitive abilities did not show the expected high correlation with the SIP-Alertness Behaviour dimension (r=.34, ns). This correlation was, however, higher than the correlations seen with scales measuring other traits (physical, emotional, social and employment), in line with the MTMM hypothesis. GRS3 also correlated highly with two other GRS scales, namely GRS5 (r=0.41, ns) and GRS1 (r=0.50, p<.01). These correlations may reflect method artefact or true correlations with satisfaction with social life (GRS5) and life in general (GRS1).

GRS4, a self-assessment of satisfaction with social functioning (including relationships with family and friends and social activities) showed, as hypothesised, a high correlation with MACL Depression scores (r=0.68, p<.001)

Table 6.56: Multi-trait, multi-method matrix based on hypothesised correlations between specified independent measures of functioning. Baseline data (n=25).

| | Physical | | Cognitive | | Emotional | | | Social | | Econ/Employment | | | Global |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | GRS2 | S-PH | GRS3 | S-AB | GRS4 | M-D | S-EM | GRS5 | S-SI | GRS6 | GRS7 | S-WK | GRS1 |
| GRS2 | | | | | | | | | | | | | |
| S-PH | .71** | | | | | | | | | | | | |
| GRS3 | .08 | .03 | | | | | | | | | | | |
| S-AB | .23 | .51* | .34 | | | | | | | | | | |
| GRS4 | -.07 | -.03 | .28 | .46 | | | | | | | | | |
| M-D | -.01 | .11 | .26 | .49* | .68** | | | | | | | | |
| S-EM | .70** | .41 | -.09 | -.03 | .003 | .13 | | | | | | | |
| GRS5 | .36 | .28 | .41 | .59** | .61** | .53* | .24 | | | | | | |
| S-SI | .21 | .40 | -.03 | .52* | .53* | .66** | .29 | .59** | | | | | |
| GRS6 | .34 | .43 | .09 | .31 | .37 | .48* | .15 | .32 | .43 | | | | |
| GRS7 | .49* | .21 | .16 | -.03 | .06 | -.02 | .19 | .22 | -.10 | .29 | | | |
| S-WK | .47* | .44 | .07 | .19 | -.26 | .05 | .40 | .17 | .14 | .38 | .01 | | |
| GRS1 | .12 | .37 | .50* | .36 | .26 | .17 | -.03 | .38 | .21 | .29 | .14 | .09 | |
| STOT | .64** | .82** | -.04 | .63** | .27 | .47* | .59* | .50* | .73** | .50* | .09 | .50* | .24 |

* p<.01 ** p<.001

Physical measures : GRS2, satisfaction with physical abilities; S-PH, SIP physical composite score.
Cognitive measures: GRS3, satisfaction with cognitive abilities; S-AB, SIP alertness behaviour.
Emotional measures: GRS4, satisfaction with emotions; M-D, MACL depression scale; S-EM, SIP emotions.
Social measures : GRS5, satisfaction with social life; S-SI, SIP social interaction.
Econ/Work measures: GRS6, satisfaction with employment; GRS7, satisfaction with finances; S-WK, SIP work dimension.
Global measures : GRS1, satisfaction with life in general; STOT, SIP total score (composite measure).

(Table 6.56). A low correlation, however, with the SIP-Emotional dimension was seen (r=0.003, ns). Other correlations of note were with GRS5 (satisfaction with social functioning) (r=0.61, p<.001) and the SIP-Social interaction dimension (r=0.53, p<.01). This suggests a link between emotional status and satisfaction with social functioning. These correlations, however, were lower than between GRS4 and the MACL Depression scale, thus the correlations are in the hypothesised order. A modest, though non-significant correlation was seen between GRS4 and GRS6 (satisfaction with employment/daytime activity) (r=0.37, ns). All other correlations were low (r < .30) and non-significant.

GRS5 (satisfaction with social life) correlated highly and significantly with the SIP-Social interaction scale (r=0.59, p<.001) and with the SIP-total disability score (r=0.50, p<.001). All other correlations were lower, thus supporting the MTMM hypothesis.

GRS6 (satisfaction with employment) showed a low correlation with GRS7 (satisfaction with financial state) (r=0.29, ns). A slightly higher, though non-significant correlation was seen between GRS6 and the SIP-Work dimension (r=0.38, ns). GRS7 did not correlate with the SIP-Work dimension (r=0.01). These findings raise questions about the validity of these measures as latent indicators of feelings about economic and employment aspects of quality of life. GRS6 showed higher correlations with measures of physical ability (SIP-Phys, r=0.43, ns), emotional status (MACL-D, r=0.48, p<.01) and general disability (SIP-total, r=.50, p<.001) than with measures of the same trait (GRS7, SIP-Work), while GRS7 correlated highly with SIP-Phys (r=0.49, p<.01). It is

interesting that similar correlations were also seen for the SIP-Work dimension (the other variable assessing employment/economic situation). SIP-Work correlated with both SIP-Phys (r=0.47, p<.01) and SIP total (r=0.50, p<.01), though these latter correlations may be due to similarity in method (all within-method correlations).

Regarding the possibility of method artefact (that is, high correlations due to similarity of method), the GRS within-method correlations were generally low indicating that method artefact is minimal. Only 4 of the within-method correlation were significant (GRS4/GRS5,r=.61, p<.001; GRS1/GRS3, r=.50, p<.01; GRS2/GRS7, r=.49, p<.01; GRS3/GRS5, r=.41, p<.04) (see Table 6.57).

### 6.4.d.ii **Sickness Impact Profile**

The SIP-Phys category score showed an expected high correlation with GRS2 (satisfaction with physical ability) (r=0.71, p<.001) (see Table 6.56), supporting the validity of this measure as a latent indicator of physical function. High, significant correlations were also noted between SIP-Phys and SIP-Alertness behaviour (r=0.51, p<.001) and SIP-Total composite score (r=0.82, p<.001) (Table 6.56).

SIP-Alertness behaviour (SIP-AB) showed a moderate but non-significant correlation with GRS3 (satisfaction with cognitive abilities) (r=0.34, ns). Higher correlations were evident between this measure and other trait measures, suggesting poor validity of this scale as a measure of cognitive ability. A significant correlation was seen between SIP-AB and the MACL Depression sub-scale (r=0.49, p<.01) and a moderate, though non-significant correlation with GRS4

Table 6.57: Global rating scale: within-method correlations, Study 2 baseline data (n=25).

| | | GRS1 | GRS2 | GRS3 | GRS4 | GRS5 | GRS6 |
|---|---|---|---|---|---|---|---|
| GRS2 | r | .12 | | | | | |
| | p | .58 | | | | | |
| GRS3 | r | .50 | .08 | | | | |
| | p | .01 | .72 | | | | |
| GRS4 | r | .26 | -.07 | .28 | | | |
| | p | .21 | .73 | .18 | | | |
| GRS5 | r | .38 | .36 | .41 | .61 | | |
| | p | .06 | .08 | .04 | .001 | | |
| GRS6 | r | .29 | .34 | .09 | .37 | .32 | |
| | p | .17 | .10 | .67 | .07 | .12 | |
| GRS7 | r | .14 | .49 | .16 | .06 | .22 | .29 |
| | p | .51 | .01 | .45 | .77 | .30 | .16 |

GRS1, life in general; GRS2, physical ability; GRS3, cognitive ability; GRS4, emotional status; GRS5, social life; GRS6, employment; GRS7, finances.

(satisfaction with social functioning) (r=0.59, p<.001). High correlations between SIP-AB and several other SIP dimensions were noted: SIP-Phys (r=0,51, p<.01), SIP-SI (r=0.52, p<.01) and SIP-Total (r=0.63, p<.001).

SIP-Emotions showed very low correlations with the other measures of emotional behaviour (GRS4, r=.003, ns; MACL-D, r=0.13, ns), raising doubts about its validity. Moderate to high correlations were seen with measures of physical ability (GRS2, r=0.70, p<.001; SIP-Phys, r=0.41, ns) and with general disability (SIP-Total, r=0.59, p<.01). Correlations with all other measures were also low, ranging from -.09 (GRS3, cognitive ability) to 0.40 (SIP-Work).

SIP-Social interaction correlated highly, as hypothesised, with GRS5 (satisfaction with social functioning) (r=0.59, p<.001). Other significant correlations included: SIP-Total (r=0.73, p<.001), MACL-D (r=0.66, p<.001), GRS4 (satisfaction with emotional state) (r=0.53, p<.01) and SIP-AB (r=0.52, p<.01). SIP-SI thus appears to be a valid measure of social functioning, with links between social functioning and emotional state and cognitive functioning being evident.

SIP-Work showed low correlations with independent measures of satisfaction with work and finances (GR6, r=03,8, ns; GRS7, r=0.01, ns). Generally, low correlations were seen between SIP-Work and other measures, the exceptions being moderate correlations with SIP-Total (r=0.50, p<.01), GRS2 (satisfaction with physical abilities) (r=0.47, p<.01), SIP-Phys (r=0.44, ns) and SIP-Em (r=0.40, ns). This raises a query as to the validity of this measure as an indicator of work-related quality of life.

Table 6.58: Within-method correlations for SIP dimensions.

| | AMB | BCM | MOB | SI | COM | AB | EM | SR | REC | EAT | HM |
|---|---|---|---|---|---|---|---|---|---|---|---|
| AMB | 1.0 | | | | | | | | | | |
| BCM | .48 | 1.0 | | | | | | | | | |
| MOB | .36 | .37 | 1.0 | | | | | | | | |
| SI | .06 | .56* | .28 | 1.0 | | | | | | | |
| COM | .19 | .55* | .27 | .37 | 1.0 | | | | | | |
| AB | .20 | .43 | .29 | .20 | .33 | 1.0 | | | | | |
| EM | -.06 | .50* | .25 | .60* | .55* | .18 | 1.0 | | | | |
| SR | .44 | .51* | .36 | .39 | .42 | .33 | .39 | 1.0 | | | |
| REC | .17 | .46 | .47 | .37 | .27 | .08 | .42 | .45 | 1.0 | | |
| EAT | .02 | .15 | -.07 | .21 | .06 | -.04 | .31 | .22 | .38 | 1.0 | |
| HM | .23 | .41 | .44 | .36 | .42 | .31 | .32 | .36 | .50* | .12 | 1.0 |
| WRK | .07 | .42 | .35 | .48 | .28 | .02 | .21 | .22 | .21 | .19 | .27 |

Spearmans correlations, same patients as in MTMM matrix (epilepsy patients, n=25).

* $p<.01$

The SIP showed a number of significant within-method correlations (22/66, see Table 6.58) suggesting high method artefact and/or non-independence of scales.

### 6.4.d.iii **Mood Adjective Checklist: Depression scale**

MACL-Depression was chosen a priori to act as a measure of emotional status. This scale correlated highly with GRS4 (satisfaction with emotional state) ($r=0.68$, $p<.001$) but poorly with SIP-Emotions ($r=0.003$, ns). Thus the MTMM validity hypothesis is partially supported. Other significant correlations include SIP-SI ($r=0.66$, $p<.001$), GRS5 (satisfaction with social functioning) ($r=0.53$, $p<.01$), SIP-AB ($r=0.49$, $p<.01$), GRS6 (satisfaction with employment ($r=0.48$, $p<.01$).

Looking at the MACL in general, a number of significant within-method correlations were seen for the MACL sub-scales (Anxiety, Fatigue, Hostility, Vigour, Depression) (See Table 6.59). The depression scale correlates highly with anxiety ($r=0.7$, $p<.000$), fatigue ($r=0.63$, $p<.001$) and hostility ($r=0.61$, $p<.001$).

Table 6.59: MACL: Within-method correlations.

| | | Anxiety | Fatigue | Hostility | Vigour |
|---|---|---|---|---|---|
| Fatigue | r | .56 | | | |
| | p | .003 | | | |
| Hostility | r | .50 | .41 | | |
| | p | .01 | .04 | | |
| Vigour | r | -.16 | -.09 | -.30 | |
| | p | .45 | .66 | .15 | |
| Depression | r | .73 | .64 | .61 | -.22 |
| | p | .000 | .001 | .001 | .30 |

Pearson correlations, epilepsy patients baseline data. Same patients as in MTMM correlation matrix (n=25).

### 6.4.e Sensitivity/discriminant validity

#### 6.4.e.i Global rating scale

Study 1 patients did not complete the GRS so sensitivity analysis is restricted to Study 2 epilepsy and trigeminal neuralgia patients (Study 3).

Study 2 data (epilepsy patients): a summary of the correlations between change in LES scores and change in GRS ratings is given in Table 6.63. Full details of all correlations can be found in Appendices 36 - 39. In general, low correlations between all life event measures (negative events, positive events, total number of events, positive/negative discrepancy) and GRS scores were seen, with mean correlations ranging from -0.23 to 0.28 (see Table 6.60).

However, a number of moderate, significant correlations for individual session pairings were seen. GRS1 (satisfaction with life in general) and GRS7 (satisfaction with finances) showed a positive correlation with the change in number of negative life events occuring between sessions 1 and 2 (GRS1, $r=0.45$, $p<.03$; GRS7, $r=0.42$, $p<.05$). In constrast, GRS3 (satisfaction with cognitive abilities) showed a significant, negative correlation with change in negative life events for the same period (GRS3, $r=-0.44$, $p<.04$) (see Appendix 36).

Significant correlations with changes in positive life events were seen for GRS6 (satisfaction with employment) (GRS6/LESP, S2vS3, $r=0.53$, $p<.01$), while negative correlations were seen for GRS 4 (satisfaction with emotions) (GRS4/LESP, S1 v S3, $r=-0.46$, $p<.03$) (see Appendix 37 for details).

Changes in total number of life events correlated positively with satisfaction with employment (GRS6/LEST, S2vS3, $r=0.45$, $p<.03$) and negatively with satisfaction with

Table 6.60: Summary of correlations between life events and change in GRS ratings (averaged across all session pairings). Epilepsy patients with complete data on all 4 occasions (n=22)

| | NEGATIVE EVENTS | POSITIVE EVENTS | TOTAL EVENTS | DISCREPANCY SCORE |
|---|---|---|---|---|
| | Mean(Range) | Mean(Range) | Mean(Range) | Mean(Range) |
| GRS1 | .11(-.02,.45) | .12(-.11,.39) | .09(-.03,.26) | -.03(-.17,.04) |
| GRS2 | .04(-.33,.27) | .05(-.31,.23) | .10(-.23,.34) | .09(-.16,.31) |
| GRS3 | -.06(-.44,.38) | .08(-.10,.25) | .05(-.25,.34) | .02(-.17,.37) |
| GRS4 | -.01(-.20,.23) | -.19( .46,-.01) | -.19(-.46,.04) | -.26(-.48,-.10) |
| GRS5 | .05(-.16,.30) | -.23(-.39,-.05) | -.18(-.41,.06) | -.21(-.45,.04) |
| GRS6 | .09(-.10,.30) | .30( .08,.45) | .28( .08,.45) | .12(-.17,.39) |
| GRS7 | -.04(-.27,.42) | .08(-.11,.27) | .04(-.27,.32) | -.02(-.25,.18) |
| TOT | .03(-.44,.45) | .03(-.39,.45) | .03(-.46,.45) | -.04(-.48,.39) |

GRS1, life in general; GRS2, physical ability; GRS3, cognitive ability; GRS4, emotions; GRS5, social life; GRS6, employment; GRS7, finances; TOT, mean total correlation (averaged over all GRS ratings).
Based on Spearmans rank order correlations.

NOTE: Means take sign of correlation into account

emotions and social life (GRS4/LEST, S1vS3, r=-0.46, p<.03; GRS5, S1vS3, r=-0.41, p<.06) (see Appendix 38).

The change in life events discrepancy score (LESD) between sessions 2 and 3 correlated positively with satisfaction with employment (GRS6/LESD, S2vS3, r=0.50, p<.02, Appendix 39). No other correlations for this measure were significant.

These correlations between changes in GRS and LES scores, however, are isolated with the majority of correlations being much smaller than this. On balance, change in life events (as measured by the LES) appears to have little effect on GRS ratings.

Study 3 data (trigeminal neuralgia patients): the means and standard deviations of the GRS ratings obtained pre- and post-operatively are listed in Table 6.61, with a summary of the t-test results given in Table 6.62. Taking a strict measure of probability (p<.002, Bonferroni correction) only GRS4 (Emotions) show significant change pre- to post-operatively. The other scales show trends in the expected direction, that is, improvement following surgery. Two notable exceptions are GRS6 (Employment) and GRS7 (Finances) which seem to be unaltered by relief of trigeminal neuralgia.

### 6.4.e.ii **Sickness Impact Profile**

Study 2 data (epilepsy patients): a summary of the mean correlations between SIP scores and change in life event scores is given in Table 6.63.

Table 6.61: Means, standard deviations, medians and ranges of GRS ratings for trigeminal neuralgia patients, pre- and post-operatively.

| | | SUCCESS (n=8) | | FAILURE (n=3) | |
|---|---|---|---|---|---|
| | Statistic | Pre-op | Post-op | Pre-op | Post-op |
| GRS1 | Mean (SD) | 3.6 (1.3) | 1.9 (1.4) | 3.3 (2.1) | 3.0 (1.7) |
| | Med (Range) | 3.5 (2-5) | 1.5 (1-5) | 4.0 (1-5) | 2.0 (2-5) |
| GRS2 | Mean (SD) | 3.5 (1.6) | 2.4 (1.4) | 4.3 (1.2) | 2.7 (2.1) |
| | Med (Range) | 4.0 (1-5) | 2.0 (1-5) | 5.0 (3-5) | 2.0 (1-5) |
| GRS3 | Mean (SD) | 3.4 (1.2) | 1.8 (1.4) | 3.7 (1.5) | 3.0 (1.0) |
| | Med (Range) | 3.0 (2-5) | 1.0 (1-5) | 4.0 (2-5) | 3.0 (2-4) |
| GRS4 | Mean (SD) | 4.0 (1.1) | 1.8 (1.4) | 3.7 (1.5) | 2.7 (2.1) |
| | Med (Range) | 4.0 (2-5) | 1.0 (1-5) | 4.0 (2-5) | 2.0 (1-5) |
| GRS5 | Mean (SD) | 3.4 (1.5) | 1.8 (1.4) | 4.0 (1.7) | 2.7 (2.1) |
| | Med (Range) | 4.0 (1-5) | 1.0 (1-5) | 5.0 (2-5) | 2.0 (1-5) |
| GRS6 | Mean (SD) | 2.9 (1.6) | 2.0 (1.3) | 3.3 (1.5) | 2.3 (1.5) |
| | Med (Range) | 2.5 (1-5) | 2.0 (1-5) | 3.0 (2-5) | 2.0 (1-4) |
| GRS7 | Mean (SD) | 2.9 (1.1) | 2.5 (1.1) | 3.3 (1.5) | 3.0 (1.0) |
| | Med (Range) | 3.0 (1-4) | 2.0 (1-4) | 3.0 (2-5) | 3.0 (2-4) |

Note: FAILURE group means given for illustrative purposes. No formal analyses conducted due to small group numbers.

Table 6.62: Summary of results of Student t-tests (paired) comparing pre- and post-operative GRS ratings.

| | SUCCESS GROUP(N=8) | |
|---|---|---|
| | t | p |
| GRS1 | 3.13 | .02 |
| GRS2 | 2.18 | .07 |
| GRS3 | 3.53 | .01 |
| GRS4 | 4.02 | .005 |
| GRS5 | 2.88 | .024 |
| GRS6 | 1.02 | .34 |
| GRS7 | 0.8 | .44 |

Note: formal analyses not conducted on FAILURE group due to small N (n=3).

Mean correlations for all SIP dimension scores are low, ranging from -0.29 to 0.25 (see Table 6.63). The correlations for the individual session pairings are given in Appendices 40-43. As indicated by the mean correlations, the majority of correlations were low, however, a number were of a magnitude to warrant further mention. Change in negative life events between sessions 3 and 4 (a period of 3 months) showed positive, significant correlations with changes in the scores of a number of SIP dimensions (MOB, $r=0.50$, $p<.02$; BCM, $r=0.42$, $p<.04$; SI, $r=0.51$, $p<.01$; AB, $r=0.50$, $p<.02$; EM, $r=0.41$, $p<.05$; SR, $r=0.40$, $p<.06$) (See Appendix 40 for details). Scores relating to social interaction and recreation also showed moderate correlations with negative life events between sessions 2 and 4 (a period of 5 months) (S2vS4: SI/LESN, $r=0.43$, $p<.04$; REC/LESN, $r=0.48$, $p<.02$), while bodycare and movement correlated with changes in negative life events between sessions 2 and 3 (S2vS3, BCM/LESN, $r=0.43$, $p<.04$).

A number of negative correlations between change in SIP scores relating to ambulation, alertness and recreation and change in positive life events (LESP) were seen (S2vS4, 5 months: AMB/LESP, $r=-0.43$, $p<.04$; AB/LESP, $r=-0.43$, $p<.04$: S2vS3, 2 months: REC/LESP, $r=-0.46$, $p<.03$). This suggests that an increase in positive life events was associated with higher scores on the SIP (indicating poorer performance). In contrast, a measure of communication ability showed a positive correlation with change in positive life events (S3vS4, 3 months: COM/LESP, $r=0.41$, $p<.05$).

A number of correlations between change in total life events and the life event disrepancy score and changes in SIP

Table 6.63: Summary of correlations between life events and change in SIP dimension scores (averaged across all session pairings). Epilepsy patients with complete data on all 4 occasions (n=23)

| | NEGATIVE EVENTS | | POSITIVE EVENTS | | TOTAL EVENTS | | DISCREPANCY SCORE | |
|---|---|---|---|---|---|---|---|---|
| | Mean | Range | Mean | Range | Mean | Range | Mean | Range |
| AMB | .25 | -.03,.36 | -.16 | -.43,.16 | -.008 | -.24,.27 | -.29 | -.52,-.1 |
| MOB | .10 | -.27,.42 | -.08 | -.29,.29 | .05 | -.34,.40 | -.14 | -.46,.17 |
| BCM | .11 | -.17,.43 | .06 | -.18,.26 | .16 | -.02,.40 | -.02 | -.45,.33 |
| SI | .12 | -.25,.51 | -.19 | -.33,.00 | -.03 | -.21,.10 | -.20 | -.52,.04 |
| COM | -.02 | -.22,.35 | .22 | .07,.52 | .25 | -.03,.45 | .18 | -.14,.39 |
| AB | .16 | -.17,.50 | -.14 | -.43,.00 | .007 | -.18,.34 | -.22 | -.49,.04 |
| EM | .16 | -.09,.41 | .005 | -.30,.31 | .13 | -.22,.34 | -.17 | -.46,.17 |
| SR | .08 | -.19,.40 | .009 | -.29,.23 | .07 | -.38,.27 | -.04 | -.23,.13 |
| EAT | .07 | -.20,.19 | .05 | -.21,.36 | .10 | -.11,.47 | -.06 | -.19,.04 |
| HM | -.005 | -.28,.26 | .18 | .04,.35 | .16 | -.01,.38 | .15 | -.08,.36 |
| REC | .18 | -.17,.48 | -.15 | -.46,.02 | .03 | -.20,.25 | -.27 | -.46,.01 |
| WORK | .00 | -.33,.51 | .12 | -.11,.32 | .09 | -.18,.36 | .08 | -.19,.30 |
| TOTAL | .10 | -.33,.51 | -.006 | -.46,.52 | .08 | -.38,.47 | -.08 | -.52,.39 |

NOTE: Means take sign of correlation into account

Table 6.64: Summary of correlations between life events and change in SIP category scores (averaged across all session pairings). Epilepsy patients with complete data on all 4 occasions (n=23)

| | NEGATIVE EVENTS | | POSITIVE EVENTS | | TOTAL EVENTS | | DISCREPANCY SCORE | |
|---|---|---|---|---|---|---|---|---|
| | Mean | Range | Mean | Range | Mean | Range | Mean | Range |
| PHYS | .19 | -.20,.48 | .02 | -.33,.36 | .13 | -.02,.40 | -.10 | -.58,.29 |
| SOC | .08 | -.22,.48 | -.15 | -.20,.09 | .02 | -.25,.32 | -.15 | -.46,.13 |
| SIP | .22 | .05,.61 | -.01 | -.42,.04 | .07 | -.24,.25 | -.22 | -.56,-.05 |
| TOTAL | .16 | -.22,.61 | -.09 | -.42,.36 | .07 | -.25,.40 | -.16 | -.58,.29 |

NOTE: Means take sign of correlation into account

Table 6.65: SIP - means, standard deviations, medians and ranges for trigeminal neuralgia patients obtained pre- and post-operatively.

| | Statistic | SUCCESS (N=8) | | FAILURE (N=3) | |
|---|---|---|---|---|---|
| | | Pre-op | Post-op | Pre-op | Post-op |
| AMB | Mean (SD) | 3.14 (4.9) | 1.7 (3.6) | 7.3 (7.8) | 0 (0) |
| | Med (Range) | 0 (0-12) | 0 (0-10) | 6 (0-16) | 0 (n/a) |
| MOB | Mean (SD) | 12.7(20.2) | 0 (0) | 12 (4.7) | 0 (0) |
| | Med (Range) | 0 (0-54) | 0 (n/a) | 11 (8-17) | 0 (n/a) |
| BCM | Mean (SD) | 2.5 (5.9) | 1.8 (4.1) | 6.2 (6.1) | 2.1 (3.7) |
| | Med (Range) | 0 (0-17) | 0 (0-12) | 6 (0-12) | 0 (0-6) |
| SI | Mean (SD) | 25.9(25.8) | 1.6 (4.5) | 10.9 (3.8) | 11.9 (6.2) |
| | Med (Range) | 20 (2-77) | 0 (0-13) | 9 (9-15) | 13 (5-18) |
| COM | Mean (SD) | 22.9(22.7) | 0 (0) | 9.5 (2.6) | 2.9 (5) |
| | Med (Range) | 23 (0-61) | 0 (n/a) | 9 (7-12) | 0 (0-9) |
| AB | Mean (SD) | 31.1(32.1) | 6.4 (18) | 6.7 (5.8) | 7.7 (6.7) |
| | Med (Range) | 23 (0-100) | 0 (0-51) | 10 (0-10) | 11 (0-12) |
| EM | Mean (SD) | 20.9(18.1) | 6.4 (15) | 20.6 (10.5) | 21.4 (13.6) |
| | Med (Range) | 22 (0-39) | 0 (0-43) | 25 (9-28) | 18 (10-36) |
| SR | Mean (SD) | 22.4(17.7) | 5 (7) | 11.8 (2.4) | 8.3 (7.5) |
| | Med (Range) | 15 (0-50) | 0 (0-15) | 10 (10-15) | 10 (0-15) |
| EAT | Mean (SD) | 10.2(14.0) | 2.8 (4) | 4.1 (3.8) | 1.6 (2.8) |
| | Med (Range) | 5 (0-39) | 0 (0-10) | 5 (0-7) | 0 (0-5) |
| WORK | Mean (SD) | 51.4(52.1) | 14.3 (35) | 38.4 (53.9) | 0 (0) |
| | Med (Range) | 56(0-100) | 0 (0-100) | 15 (0-100) | 0 (n/a) |
| HM | Mean (SD) | 17.8(22.4) | 10.5 (23.9) | 21 (19.5) | 7.3 (6.3) |
| | Med (Range) | 12 (0-68) | 0 (0-68) | 11 (9-44) | 11 (0-11) |
| REC | Mean (SD) | 23.8(24.7) | 9.1 (22.9) | 20.1 (11.1) | 20.7 (23.3) |
| | Med (Range) | 13 (0-65) | 0 (0-65) | 25 (7-28) | 16 (0-46) |
| PHYS | Mean (SD) | 4.7(7.5) | 1.4 (3.1) | 7.6 (4.4) | 1.1 (2) |
| | Med (Range) | 2.3 (0-22) | 0 (0-9) | 7 (3 -12) | 0 (0-3) |
| SOC | Mean (SD) | 25.2(23.1) | 3.3 (8.5) | 11.7 (2.6) | 11.1 (2.7) |
| | Med (Range) | 21 (3-70) | 0 (0-24) | 11 (10-15) | 10 (9-14) |
| SIP | Mean (SD) | 18.7(20.9) | 3.8 (7.2) | 11.6 (2.5) | 6.2 (2) |
| | Med (Range) | 13 (3-66) | 0.9 (0-21) | 12 (9-14) | 6 (5-9) |

AMB, ambulation; MOB, mobility; BCM, bodycare and movement; SI, social interaction; COM, communication; AB, alertness behaviour; EM, emotions; SR, sleep and rest; EAT, eating, WORK, work; HM, household management; REC, recreation; PHYS, physical disability score; SOC, psychosocial disability score; SIP, total disability score; n/a, not applicable

data were seen. These varied across SIP dimension scores and session pairings with no discerable pattern (see Appendices 42 and 43.

Similarly, the SIP category scores (physical disability, psychosocial disability and total disability), while generally showing a low association with LES scores, did demonstrate significant correlations in a small number of cases. A summary of these data is given in Table 6.64.

In summary, these data suggest that certain scales of the SIP may be sensitive to the occurrence of life events in patients with epilepsy.

Study 3 data (trigeminal neuralgia patients): full details of pre- and post-operative SIP sub-scale and category scores can be found in Table 6.65. No significant change at the 0.01 level was seen in pre- to post-operative SIP sub-scale scores in patients with successful operations. (See Appendix 44 for details of the results of these analyses).

6.4.d.iii **Mood Adjective Checklist**

Study 2 data (epilepsy patients): low mean correlations (summed over all session pairings) were seen between all MACL sub-scales (anxiety, fatigue, hostility, vigour, depression) and negative, positive, total and discrepancy life events scores (Negative events, overall mean correlation, r=.06, range=-.46 to .45; Positive events, overall mean correlation, r=.04; range=-.37 to .44; Total events, overall mean correlation, r=.09, range=-.29 to .51; Discrepancy score, overall mean correlation, r=.004, range=-.46 to .53) (Table 6.66). The Vigour sub-scale showed a significant correlation

at the .01 level with the life event discrepancy score between S2 (1 month) and S4 (6 months) ($r=.53$, $p<.007$; Appendix 48). All other correlations were lower than 0.50 (Spearmans rho) and were non-significant at the .01 level. Full details of correlations with life event data can be found in Appendices 45 to 48.

Study 3 data (trigeminal neuralgia patients): 3 of the 5 MACL sub-scales discriminated between pre- and post-operative trigeminal neuralgia patients in whom the operation had been successful in removing the pain, notably scales measuring anxiety, fatigue and depression. The hostility and vigour scales failed to reach significance (see Table 6.67 for details of the findings of this analysis). Details of the pre- and post-operative scores for both successful and non-successful operation patients are given in Table 6.68. These data suggest that the MACL is a sensitive measure in detecting changes in levels of anxiety, fatigue and depression in post-operative trigeminal neuralgia patients.

Table 6.66: MACL Sensitivity Analysis: summary of correlations between life events and change in MACL ratings (averaged across all session pairings). Epilepsy patients with complete data on all 4 occasions (n=24).

| | NEGATIVE EVENTS<br>Mean (Range) | POSITIVE EVENTS<br>Mean (Range) | TOTAL EVENTS<br>Mean (Range) | DISCREPANCY SCORE<br>Mean (Range) |
|---|---|---|---|---|
| Anx | .20 (-.21,.45) | .11 (-.05,.44) | .24 (-.08,.51) | -.06 (-.46,.02) |
| Fat | -.09 (-.29,.12) | .03 (-.37,.21) | -.04 (-.29,.17) | .11 (-.24,.43) |
| Hos | .22 ( .01,.40) | .03 (-.14,.12) | .19 (-.01,.34) | -.11 (-.26,.04) |
| Vig | -.07 (-.46,.40) | .15 (-.11,.37) | .10 (-.28,.41) | .17 (-.17,-.53) |
| Dep | .04 (-.17,.25) | -.10 (-.35,.08) | -.04 (-.18,.09) | -.09 (-.31,.20) |
| TOT | .06 (-.46,.45) | .04 (-.37,.44) | .09 (-.29,.51) | .004(-.46,.53) |

Anx, anxiety; Fat, fatigue; Hos, hostility; Vig, vigour; Dep, depression; TOT, mean total correlation (averaged over all scales).

Spearman correlations.

NOTE: Means take sign of correlation into account

Table 6.67: Summary of results of Student t-tests (paired) comparing pre- and post-operative MACL scores.

| | SUCCESS GROUP(N=8) | |
|---|---|---|
| | t | p |
| Anx. | 3.27 | .01 |
| Fat. | 2.81 | .03 |
| Host. | 2.05 | .08 |
| Vig. | -1.92 | .10 |
| Dep. | 2.63 | .04 |

Note: formal analyses not conducted on FAILURE group due to small N (n=3).

Table 6.68: MACL - means, standard deviations, medians and ranges for trigeminal neuralgia patients obtained pre- and post-operatively.

| Statistic | | SUCCESS (N=8) | | FAILURE (N=3) | |
|---|---|---|---|---|---|
| | | Pre-op | Post-op | Pre-op | Post-op |
| Anx. | Mean (SD) | 5.1 (3.6) | 1.3 (1.4) | 6.0 (3.0) | 3.7 (3.8) |
| | Med (Range) | 4.5 (0-10) | 1.0 (0-3) | 6.0 (3-9) | 2.0 (1-8) |
| Fat. | Mean (SD) | 7.6 (3.7) | 3.9 (3.0) | 3.0 (1.7) | 3.7 (3.1) |
| | Med (Range) | 8.5 (0-11) | 3.0 (0-10) | 2.0 (2-5) | 3.0 (1-7) |
| Host. | Mean (SD) | 1.4 (1.6) | 0.6 (1.2) | 1.0 (1.0) | 1.7 (1.5) |
| | Med (Range) | 1.0 (0-4) | 0.0 (0-3) | 1.0 (0-2) | 2.0 (0-3) |
| Vig. | Mean (SD) | 1.8 (1.4) | 3.9 (3.2) | 0.7 (1.2) | 3.3 (3.1) |
| | Med (Range) | 2.0 (0-4) | 3.5 (0-8) | 0.0 (0-2) | 4.0 (0-6) |
| Dep. | Mean (SD) | 7.6 (7.8) | 2.9 (6.2) | 7.7 (4.5) | 5.0 (7.8) |
| | Med (Range) | 6.0 (0-21) | 0.5 (0-18) | 8.0 (3-12) | 1.0 (0-14) |

Anx., anxiety; Fat., fatigue; Hos., hostility; Vig., vigour; Dep., depression.

Note: FAILURE group means given for illustrative purposes. No formal analyses conducted due to small group numbers.

# CHAPTER 6

# RESULTS

## 6.5. INFLUENCE OF EPILEPSY VARIABLES

## 6.5 INFLUENCE OF EPILEPSY VARIABLES ON RG-BASED MEASURES OF QOL

### 6.5.a Age of onset

#### 6.5.a.i Aggregate RG measures

Significant correlations at the 0.05 level of significance were seen between age of onset and 2 of the 5 aggregate measures (ABS6, $r=0.30$, $p<.018$; ABS21, $r=0.27$, $p<.029$). However, the magnitude of the correlations were small and thus cautious interpretation of these data is required. Means for these variables for early and late onset groups (classified by dividing patients into those above and those below the median age of onset) suggest that late onset epilepsy is associated with higher RG scores and thus poorer QOL (Means: Early onset - ABS6, mean=3.95, SD=1.32; ABS21, mean=11.21, SD=5.26: Late onset - ABS6, mean=4.56, SD=1.25; ABS21, mean=13, SD=5.39).

#### 6.5.a.ii Profile scores (methods 1 and 2)

No significant association between age of onset of epilepsy and RG profile scores (calculated by either method).

### 6.5.b Duration of epilepsy

No significant association was seen between duration of epilepsy and either aggregate or profile RG scores. This suggests that this variable has a minimal impact on current QOL.

### 6.5.c Aetiology

Comparison of the RG scores (aggregate and profile) according to whether aetiology was known or not revealed no significant group differences. In addition, a more detailed analysis in which the various known causes (trauma, prolonged childhood convulsion, birth injury/hypoxia, cerebral infection, familial, tumour, congenital malformation, infarction/haemorrhage, infection plus familial) were included showed no group differences.

### 6.5.d History of status/Family history of epilepsy

Having a history of status epilepticus or having a family history of epilepsy (generally regarded as indicants of severe epilepsy) did not influence any of the RG measures (aggregate, profile scores method 1, profile scores method 2).

6.5.e **EEG focus**

The influence of the site of epileptic activity (as determined by EEG findings) on QOL scores was investigated. No significant findings were seen for either the aggregate (ABS, DIR, ABS6, DIR6, ABS21) or profile measures (PHYS1, COG1, EMOT1, SOC1, WORK1, PHYS2, COG2, EMOT2, SOC2, WORK2).

6.5.f **Number of seizure types**

6.5.f.i **Aggregate RG measures**

A comparison of patients experiencing only one seizure type with those having more that one type of seizure revealed no significant group differences on aggregate RG scores.

6.5.f.ii **Profile measures (methods 1 and 2)**

A significant difference on social and emotional profile scores (both methods) was seen, with lower scores (indicative of better QOL) being evident in the 1 seizure type only group. A summary of these findings is given in Table 6.69.

6.5.g **Seizure type**

The majority of patients experienced complex partial seizures with or without secondary generalisation (CPS+/-2GEN, n=41), 7 had primary generalised (2), 2 had simple partial seizures (SPS) and 2 had seizures which were unclassifiable . Table 6.70 lists the seizure types experienced by individual patients.

The SPS group were too small to be included in any formal analysis. No significant differences between the CPS+/-2GEN and PG seizure types on any of the RG measures (aggregate, profile 1 or profile 2) were seen. Table 6.71 gives details of the mean RG scores for these seizure type groupings.

6.5.h **Seizure rate**

Weekly seizure rates for the study period are given in Table 6.72. No significant fluctuation in seizure rates was seen during the course of the study, reflecting the stable nature of the population being studied (Friedmans: PG, $p<.56$; CPS, $p<.32$; 2GEN, $p<.11$). No formal analyses were performed for the simple partial seizure group (SPS) as this consisted of 2 cases only.

Table 6.69: Influence of number of seizure types on RG profile measures (baseline data, n=50)

| Variable | 1 sz type Mean (Range) | > 1 sz types Mean (Range) | M-W result Z | p |
|---|---|---|---|---|
| Method 1 | | | | |
| EMOT1 | 11.69 (1-31) | 28.11 (0-81) | -2.72 | .007 |
| SOC1 | 12.69 (1-37) | 25.49 (0-75) | -1.97 | .049 |
| Method2 | | | | |
| EMOT2 | 1.08 (0-4) | 2.49 (0-8) | -2.27 | .023 |
| SOC2 | 1.54 (0-5) | 2.84 (0-8) | -1.96 | .05 |

Key:
EMOT1, emotional profile score (method 1); SOC1, social profile score (method 1); EMOT2, emotional profile score (method 2); SOC2, social profile score (method 2); Sz, seizure; M-W, Mann-Witney U test.

Note: higher score = poorer QOL

Table 6.70: Seizure types experienced by patients in the study

| Study No | Drugs | Study No | Drugs |
|---|---|---|---|
| 1 | IC | 26 | IB, IC |
| 2 | IB, IC | 27 | IB, IC |
| 3 | IB, IC | 28 | IB, IC |
| 4 | IB, IC | 29 | IB, IC |
| 5 | IB, IC | 30 | IB, IC |
| 6 | PG | 31 | IB, IC |
| 7 | IC | 32 | IB, IC |
| 8 | IB | 33 | IB, IC |
| 9 | PG | 34 | IB, IC |
| 10 | IB, IC | 35 | IB, IC |
| 11 | IB, IC | 36 | UNCLASSIFIED |
| 12 | PG | 37 | IA, IB, I |
| 13 | PG | 38 | IB, IC |
| 14 | PG | 39 | IB, IC |
| 15 | IB, IC | 40 | IB, IC |
| 16 | IB, IC | 41 | PG |
| 17 | IB, IC | 42 | IB, IC |
| 18 | IC | 43 | IC |
| 19 | IB, IC | 44 | IB |
| 20 | IB, IC | 45 | IB |
| 21 | IB, IC | 46 | IC |
| 22 | IB, IC | 47 | IA, IB, IC |
| 23 | IB, IC | 48 | IB, IC |
| 24 | IB, IC | 49 | UNCLASSIFIED |
| 25 | PG | 50 | IB |

IA, simple partial; IB, complex partial; IC, secondary generalised; PG, primary generalised.

Table 6.71: RG scores (aggregate and profile) by seizure type groupings: means and (SDs)

| | CPS+/-2Gen (n=41) | Primary generalised (n=7) |
|---|---|---|
| Aggregate | | |
| ABS | 11.78 (8.0) | 14.0 (7.4) |
| DIR | 10.56 (8.5) | 13.4 (8.0) |
| ABS6 | 4.18 (1.40 | 4.9 (0.9) |
| DIR6 | 4.49 (1.1) | 5.0 (1.1) |
| ABS21 | 11.88 (5.3) | 14.1 (5.5) |
| Profile:Method 1 | | |
| PHYS1 | 16.0 (11.8) | 18.1 (10.4) |
| COG1 | 17.5 (14.5) | 22.3 (16.0) |
| EMOT1 | 23.8 (21.5) | 25.4 (16.8) |
| SOC1 | 21.3 (18.7) | 28.4 (22.6) |
| WORK1 | 14.8 (15.9) | 23.0 (16.6) |
| Profile: Method 2 | | |
| PHYS2 | 2.17 (1.7) | 2.29 (1.6) |
| COG2 | 2.61 (2.2) | 3.29 (2.5) |
| EMOT2 | 2.17 (2.2) | 2.29 (1.6) |
| SOC2 | 2.42 (2.1) | 3.00 (2.3) |
| WORK2 | 2.17 (2.2) | 3.00 (2.4) |

CPS, complex partial; 2GEN, secondary generalised; PHYS, physical functioning; COG, cognitive abilities; EMOT, emotional status; SOC, social functioning; WORK, economic/employment status.

Table 6.72: Weekly seizure rates during study period: means and SDs)

| | Baseline | 1 month | 3 months | 6 months |
|---|---|---|---|---|
| SPS (n=2) | | | | |
| Case 1 | 0 | 0 | 0 | 0 |
| Case 2 | 0.13 | 0.40 | 0.11 | 0.08 |
| CPS (n=28) | 1.79 (2.9) | 1.37 (2.5) | 1.51 (2.6) | 1.54 (2.0) |
| 2GEN(n=27) | 0.58 (1.7) | 0.24 (0.6) | 0.38 (1.1) | 0.31 (0.7) |
| PG (n=7) | 1.08 (1.3) | 1.09 (1.1) | 0.59 (0.5) | 0.69 (0.7) |

SPS, simple partial; CPS, complex partial; 2GEN, secondary generalised; PG, primary generalised.

Note: numbers in seizure rate analysis are lower than number of patients with that seizure type as weekly seizure rates were unavailable for a number of patients.

Table 6.73 outlines the baseline correlations between weekly seizure rate and RG scores. If seizure rate directly affects an individuals quality of life, it would be expected that a high seizure rate would be associated with poorer QOL. In general, weak associations were seen, ranging from .03 to .72, with only 1 of the 45 correlations being greater that r=0.50. A high, negative correlation between primary generalised seizure rate and the physical profile score (method 2) was seen (PG/PHYS2, r-0.72) (see Table 6.73), but this was in a group of 7 patients only and thus not significant (p=0.07).

### 6.5.i Medication

Patients in the study were taking a variety of combinations of medications, as seen in Table 6.74, and caution needs to be taken in interpreting the influence of individual AEDs on QOL scores.

#### 6.5.i.i **Aggregate RG scores**

Correlations between individual AED doses and the aggregate RG scores (ABS, DIR, ABS6, DIR6, ABS21) are given in Table 6.75. The majority of correlations are very low and of little significance, with only 1 of the 25 correlations being greater than r=0.50. Moderate, negative correlations were seen between VPA doses and 2 of the RG scores (VPA/ABS, r=-0.56; VPA/DIR, r=-0.42). This suggests that higher doses of VPA are associated with lower RG scores and by implication better QOL.

#### 6.5.i.ii **Profile scores (methods 1 and 2)**

Summaries of the correlations between AED dose and the profile scores are given in Table 6.75. As with the aggregate RG scores, the majority of correlations are low, but a number are of such a magnitude as to be of interest.

Method 1 profile scores: 3/25 of the correlations were greater than r=0.50. Moderate, negative correlations were seen between VPA dose and 4 of the 5 profile scores (VPA/WORK1, r=-0.62; VPA/EMOT1, r=-0.55; VPA/SOC1, r=-0.43; VPA/PHYS1, r=-0.34).

Table 6.73: Correlations between weekly seizure rates and RG scores; baseline data.

| | CPS (N=28) | 2GEN (N=27) | PG (N=7) |
|---|---|---|---|
| ABS | -.08 | .03 | -.20 |
| DIR | -.35 | -.07 | -.35 |
| ABS6 | -.17 | -.10 | -.11 |
| DIR6 | -.11 | -.21 | -.18 |
| ABS21 | -.13 | -.11 | -.23 |
| PHYS1 | -.04 | .06 | -.09 |
| COG1 | -.27 | -.04 | -.14 |
| EMOT1 | -.09 | -.21 | .05 |
| SOC1 | .03 | .06 | .16 |
| WORK1 | .13 | .19 | -.16 |
| PHYS2 | -.11 | -.04 | -.72 |
| COG2 | -.33 | -.07 | -.22 |
| EMOT2 | -.06 | -.28 | .04 |
| SOC2 | -.04 | .05 | .24 |
| WORK2 | .14 | .15 | -.15 |

CPS, complex partial; 2GEN, secondary generalised; PG, primary generalised; PHYS, physical functioning; COG, cognitive abilities; EMOT, emotional status; SOC, social functioning; WORK, economic/employment status.

Spearman correlations, listwise deletion employed.

Table 6.74: AED combinations taken by individual patients

| No | Drugs | No | Drugs |
|---|---|---|---|
| 1 | PHT, CLB | 26 | CBZ, VPA, CLB |
| 2 | PHT | 27 | CBZ, PRIM |
| 3 | CBZ | 28 | PHT, CBZ |
| 4 | CBZ | 29 | PHT, CBZ, CLB |
| 5 | CBZ, VPA | 30 | CBZ, VPA, CLB |
| 6 | CBZ, VPA | 31 | CBZ |
| 7 | CBZ, VPA, PRIM | 32 | CBZ, PRIM |
| 8 | PHT, PRIM | 33 | CBZ, CLB |
| 9 | PHT, PRIM | 34 | PHT, PRIM |
| 10 | CBZ | 35 | CBZ, PRIM |
| 11 | CBZ | 36 | - |
| 12 | PHT, PRIM | 37 | PHT, CBZ, CLB |
| 13 | PHT, PRIM | 38 | PHT, CBZ |
| 14 | PHT, PRIM | 39 | CBZ, CLB |
| 15 | PHT, VPA, CLB | 40 | PHT, CBZ, VPA, CLB |
| 16 | PHT, VPA, CLB | 41 | PHT, VPA, PRIM |
| 17 | PHT, CBZ | 42 | PHT, PRIM, CLB |
| 18 | PHT, CBZ | 43 | PHT |
| 19 | CBZ, VPA | 44 | PRIM |
| 20 | PHT, CBZ, VPA | 45 | PRIM |
| 21 | PHT | 46 | CBZ, VPA |
| 22 | PHT, PRIM | 47 | CBZ, VPA, CLB |
| 23 | CBZ | 48 | CBZ, VPA, PRIM |
| 24 | CBZ, VPA | 49 | - |
| 25 | CBZ | 50 | CBZ |

No, Study number; PHT, phenytoin; CBZ, carbamazepine; VPA, valproate; PRIM, primidone; CLB, clobazam

Table 6.75: Correlations between doses of individual AEDs and RG scores; baseline data.

| RG-score | PHT n=23 | CBZ n=31 | VPA n=15 | PRIM n=16 | CLB n=12 |
|---|---|---|---|---|---|
| ABS | .14 | -.05 | -.56 | -.09 | .19 |
| DIR | .16 | .01 | -.42 | .02 | .23 |
| ABS6 | -.04 | .02 | -.03 | .25 | .27 |
| DIR6 | -.09 | -.08 | -.34 | .35 | .28 |
| ABS21 | .08 | .08 | -.27 | .09 | .29 |
| PHYS1 | -.11 | .04 | -.34 | -.53 | .52 |
| COG1 | -.10 | -.05 | -.23 | -.06 | .12 |
| EMOT1 | .33 | -.09 | -.55 | -.11 | -.13 |
| SOC1 | .24 | -.03 | -.43 | -.02 | -.08 |
| WORK1 | .02 | -.11 | -.62 | -.08 | .06 |
| PHYS2 | .05 | .13 | -.31 | -.28 | .64 |
| COG2 | -.12 | -.04 | -.21 | .03 | .13 |
| EMOT2 | .21 | -.06 | -.45 | -.02 | .04 |
| SOC2 | .34 | .11 | -.33 | .04 | .10 |
| WORK2 | .05 | .81 | -.63 | -.04 | -.24 |

PHT, phenytoin; CBZ, carbamazepine; VPA, valproate; PRIM, primidone; CLB, clobazam; PHYS, physical functioning; COG, cognitive abilities; EMOT, emotional status; SOC, social functioning; WORK, economic/employment status.

In addition a moderate, positive correlations was seen between CLB dose and physical ability (CLB/PHYS1, r=0.52). This suggests less satisfaction with physical ability at high doses of CLB respectively.

Method 2 profile scores: these behaved similarly to method 1 profile scores. 2/25 of the correlations were greater that r=0.50, with VPA doses having the most influence on the profile scores. Again, moderate, negative correlations between VPA dose and selected profile scores were seen (VPA/WORK2, r=-0.63; VPA/EMOT2, r=-0.45). Moderate positive correlations were noted between CLB dose and physical ability (CLB/PHYS2, r=0.64).

These findings are similar to those seen with the method 1 profile scores, the exception being a lower correlation between VPA dose and social functioning (method 2) (VPA/SOC1, r=-0.43; VPA/SOC2, r=-0.33).

### 6.5.i.iii **Individual AEDs: mean QOL scores**

Means for all RG scores by individual AED groups are to be found in Table 6.76. There appears to be little difference between the individual AEDs, although formal analysis was not possible due to the large number of patients on polytherapy and hence non-independence of the subjects forming the individual drug groups.

### 6.5.j Monotherapy versus Polytherapy

No significant differences between those patients receiving monotherapy and those on polytherapy in terms of scores on aggregate or profile (methods 1 and 2) RG measures were seen.

Table 6.76: RG scores by individual AED groupings: means and (SDs)

| | PHT(n=23) | CBZ(n=31) | VPA(n=15) | PRIM(n=16) | CLB(n=12) |
|---|---|---|---|---|---|
| ABS | 13.2(8.3) | 11.9(7.7) | 13.7(6.9) | 9.6(6.7) | 11.3(6.1) |
| DIR | 12.4(8.6) | 10.5(8.3) | 11.9(7.3) | 8.9(6.9) | 8.6(7.4) |
| ABS6 | 4.3(1.6) | 4.4(1.2) | 4.7(1.1) | 4.1(1.3) | 4.2(1.4) |
| DIR6 | 4.7(1.3) | 4.5(1.0) | 4.8(1.1) | 4.4(1.4) | 4.4(1.1) |
| ABS21 | 12.5(6.2) | 12.6(4.9) | 13.4(4.5) | 10.7(5.5) | 11.5(4.9) |
| PHYS1 | 15.9(11.1) | 17.1(10.8) | 16.1(10.2) | 13.2(10.1) | 12.5(10.6) |
| COG1 | 20.5(15.0) | 17.5(14.7) | 21.6(15.1) | 15.3(12.5) | 20.7(15.1) |
| EMOT1 | 24.5(19.5) | 25.2(22.4) | 28.8(21.3) | 15.8(14.2) | 22.3(11.9) |
| SOC1 | 25.4(20.7) | 21.7(19.0) | 27.3(16.1) | 16.1(19.0) | 20.1(9.6) |
| WORK1 | 18.2(17.1) | 15.0(16.0) | 18.2(16.4) | 15.1(14.7) | 12.5(16.1) |
| PHYS2 | 2.4 (1.9) | 2.2 (1.5) | 2.0 (1.5) | 1.9 (1.6) | 1.7 (1.4) |
| COG2 | 3.1 (2.3) | 2.6 (2.2) | 3.2 (1.1) | 2.3 (2.0) | 3.2 (2.6) |
| EMOT2 | 2.1 (2.0) | 2.3 (2.1) | 2.5 (2.0) | 1.6 (1.6) | 2.2 (1.6) |
| SOC2 | 2.8 (2.2) | 2.5 (2.1) | 3.0 (1.5) | 1.6 (2.0) | 2.3 (1.4) |
| WORK2 | 2.5 (2.5) | 2.1 (2.1) | 2.6 (2.2) | 2.3 (2.1) | 1.8 (2.2) |

PHT, phenytoin; CBZ, carbamazepine; VPA, valproate; PRIM, primidone; CLB, clobazam; PHYS, physical functioning; COG, cognitive abilities; EMOT, emotional status; SOC, social functioning; WORK, economic/employment status.

Note 1: higher score = poorer QOL
Note 2: Maximum possible scores ABS/DIR=40; ABS6/DIR6=6; ABS21=21; PHYS1....WORK2=8.

# CHAPTER 6

# RESULTS

## 6.6. AREAS OF IMPORTANCE: CONSTRUCTS

## 6.6 AREAS OF IMPORTANCE TO QUALITY OF LIFE: CONSTRUCTS

### 6.6.a Choice of constructs

#### 6.6.a.i Epilepsy group

Details of constructs elicited within the five life domains (physical, cognitive, emotional, social and economic/employment) can be found in Table 6.77, together with the frequency of their occurence. Some of the constructs are highly individualised, however, a number of constructs which were raised by many patients, suggesting that these are areas of common concern to patients with epilepsy.

#### 6.6.a.ii Trigeminal neuralgia group

The constructs elicited from the patients with trigeminal neuralgia are listed in Table 6.78. A comparison of the areas of importance given by patients with epilepsy and those with trigeminal neuralgia is of interest as it provided an insight into what areas are of common concern, irrespective of illness, and which are illness-specific.

### 6.6.b Construct Importance

An area which seems to have received little attention is that of construct importance. How is an individuals rating of life satisfaction influenced by the importance they attach to a specific area of functioning? For example, a large change in an area of little importance may not affect overall feelings of QOL, while a small change in an area of great importance may dramatically alter overall QOL. The construct importance scale (CIS) devised and used in this study was included primarily to determine whether or not areas of importance to the individual were being elicited by the RG construct elicitation procedure. Another area of interest is the potential use of this scale to provide an individualised weighting mechanism for scoring QOLAS. If CIS ratings are to be seriously considered as a weighting variable it is important to understand how this scale performs. There are a number of questions which need to be addressed:

Table 6.77: Areas of importance provided by epilepsy group

**PHYSICAL CONSTRUCTS** (n=108)
Epilepsy (n=48); general physical ability (n=24); Fatigue/tiredness (n=15); s leep problems (n=6); incontinence (n=3); Others (1 each): arthritis; catarrh; spasticity; chest pains; diabetes; head pains; angina; back trouble; dizziness; speech; speech problems; having an illness

**COGNITIVE CONSTRUCTS** (n=94)
memory (38); concentration (18); mental speed (12);
having experience/knowledge (9); literacy skills (7); intellligence (4);
mental abilities (2); learning new things (2);
Others (1 each): organisational skills; living in past

**EMOTIONAL CONSTRUCTS** (n=138)
anger/aggression (29); depression (18); frustration (17); anxiety (13); happiness (13); confidence (8); being in control (6); boredom (5); being caring (3); sense of achievement (3); arguments (2); being understanding (2); shyness (2); having courage (2); Others (1 each) making best of things;having status; perseverence; stubborn; able to fulfil ambitions; being pitied; trusting others; feeling secure; being bossy; patience; moods; being realistic; being tolerant; being liked; being sincere; being outspoken;

**SOCIAL CONSTRUCTS** (n=159)
independence (27); going out/social life (22); making friends (19); loneliness (18); partner/marriage (17); communicating with people/getting on with people (10); family relationships (10); travel (7); family contact (6); being helpful/useful/keeping occupied (6); own home (5); able to have children (3); living on centre (3); others (1 each): living with family; sexual relationship; having shared interests; privacy; able to cook; contact with friends

**ECONOMIC/EMPLOYMENT CONSTRUCTS** (n=91)
lack of money (43); having a job/being in work (16); job satisfaction (8); having an interesting job (6); having and using skills at work (3); having a 'real' job (3); being financially independent (2); having a well-paid job (2); making ends meet (2); others (1 each): having money to save; working outdoors; problems with employer; achievement at work; fear of losing job; having enough money to keep in fashion

**OTHER CONSTRUCTS** (n=8)
politeness; being successful; doing best you can; having goals; doing duty; having opportunities; getting things done; having faith in God

Note: based on interviews with 50 patients with epilepsy.

Table 6.78 Areas of importance provided by trigeminal neuralgia group

**PHYSICAL CONSTRUCTS** (n=47)
being in pain (17); having good health (6); being physically fit/able (5); having a chronic illness (5); being able to talk (3); having trigeminal neuralgia (2); having energy (2), tiredness (2); eating (1); having physical ailment (1); arthritis (1); deafness (1); being able to drive (1).

**COGNITIVE CONSTRUCTS** (n=37)
memory (11); concentration (7); decision making (3); having qualifications (2); being able to use intellect (2); feeling slowed down mentally (2); education (2); having skills (1); intelligence (1); being capable (1); being able to study (1); having intellectual interests (1); being mentally alert (1); having self-control (1); being able to use initiative (1).

**EMOTIONAL CONSTRUCTS** (n=69)
being happy/cheerful (10), depression/feeling miserable (9); anxiety (6); control of temper/aggression (5); having positive outlook/being hopeful for future (5); being dogmatic/strong-willed (3); being relaxed/easy-going (3); having sense of humour (3); self-pity (2); having patience (2); being able to cope (2); being understood (2); being able to enjoy life (2); others (1 each): thinking of others; being grumpy, being caring, being cantankerous; feeling different to other people; being conscientious; leading a full life; being loved; being sympathetic to others; being extrovert; being pitied; being in control of life; having inner contentment; feeling apprehensive; being a perfectionist;

**SOCIAL CONSTRUCTS** (n=66)
having active social life/being able to socialise (16); having close family/good family life (9); independence/freedom (7); being able to take part in and enjoy hobbies/pastimes/sports (4)having shared interests with others (3); having friends/close friends (3); having contact with family and friends (3)being able to care for family (3); making friends/getting on with people (2); being good company/gregarious (2); having good marriage/relationship with partner (2); having close companion/someone to rely on (2); able to take part in outdoor activities (2); loneliness (2); having good relationship with partner; having support of friends (1); belonging to organisations (1); having limited social opportunities (1); boredom (1); being able to help other people (1)

**ECONOMIC/EMPLOYMENT CONSTRUCTS** (n=44)
being financially secure/free from financial worries (8); having enough money for needs (6); having an adeqate standard of living (1); having material possessions (1); being happy with finances (1); having adequate reward for work (1); being careful with money (1); being able to provide for family.

being able to work (5); keeping busy/occupied during the day (4); having a job (3); enjoying work (2); being able to do job properly (1); keeping job (1); being in control at work (1); having a rewarding job (1); having a useful job (1); having a good job (1); being able to organised things at work (1); being self-employed (1); having responsibility at work (1); having to take time off work (1);

**OTHER CONSTRUCTS** (n=19)
taking medication (5), being able to plan things (3); having basic needs met; having responsibilities; being polite; having determination; putting on a front; being honest; taking things in stride; being able to enjoy food; doing something worthwhile with life; spiritual faith; being able to take criticism.

Note: based on interviews with 19 patients.

1. Is there variation in the use of the ratings? If little variation in the use of CIS ratings is seen, then their use as a weighting method is unlikely to add much information.
2. How are they influenced by factors such as age, level of intelligence and sex of the respondent?
3. Are CIS ratings stable over time?
3. Is there any evidence of response bias? Do certain subjects have a tendency to rate all CIS ratings highly, while others rate them lowly? If response bias exists, then to use CIS ratings as a weighting variable would introduce a massive response bias into the scoring of the RG-based QOL measures.

A series of analyses were performed to address some of these issues.

6.6.b.i **Background information**

Details of means, standard deviations, medians and ranges for the CIS ratings can be found in Appendix 49. The CIS data demonstrated non-normal distributions and thus non-parametric statistics have been used.

6.6.b.ii **Are areas of importance to the individual being tapped?**

Table 6.79 outlines the distribution of the CIS ratings. On all 4 occassions, approximately 70% of patients used either the rating 4 (very important) or 5 (extremely important). Only a small percentage (1-2%) use the rating 1 (not at all important). This suggests that areas of importance to the individual are being tapped and has implications regarding the content validity of the RG method.

6.6.b.iii **Variability of CIS ratings**

An examination of Table 6.79 suggests that while a high percentage of patients used the 4 (very important) and 5 (extremely important) categories, there does appear to be variation in the use of the CIS ratings. Further investigation of individual variability in the use of CIS ratings seems warranted.

Table 6.79 Distribution of CIS ratings

| CIS rating | Session 1 Freq | % | Session 2 Freq | % | Session 3 Freq | % | Session 4 Freq | % |
|---|---|---|---|---|---|---|---|---|
| 1 | 7 | 2.3 | 5 | 1.5 | 4 | 1.2 | 5 | 1.5 |
| 2 | 25 | 8.4 | 26 | 7.9 | 23 | 7.0 | 25 | 7.3 |
| 3 | 59 | 19.8 | 53 | 16.2 | 64 | 10.5 | 7 | 20.4 |
| 4 | 145 | 48.7 | 142 | 43.3 | 159 | 48.5 | 155 | 45.2 |
| 5 | 62 | 20.8 | 102 | 31.1 | 78 | 23.8 | 88 | 25.7 |
| Tot. | 298 | | 328 | | 328 | | 343 | |

1=not important; 2=slightly important; 3=moderately important; 4=very important; 5=extremely important; Tot., total numbers of ratings (15 per subjects, except ID 35 who had 13 constructs).

### 6.6.b.iv **Influence of age and IQ**

Details of the correlations between CIS ratings and age, full-scale IQ, performance IQ and verbal IQ are given in Table 6.80. CIS10 showed a moderate, negative correlation with age (Pearson r=-.48, p<.04). All other CIS scales showed low correlations with age with coefficient values ranging from -.01 (CIS12) to .35 (CIS15). A small number of correlations with IQ measures were seen. CIS17 showed strong correlations with all IQ measures (FSIQ, r=-.71, p<.002; PIQ, r=-.50, p<.047; VIQ, r=-.66, p<.005). In addition, CIS12 demonstrated a modest correlation with performance IQ (r=-.55, p<.03).

### 6.6.b.v **Influence of gender**

No significant effects of gender were seen on CIS scores in either analysis (all epilepsy patients or matched group). Full details of the results of these analyses are given in Appendix 50.

### 6.6.b.vi **Temporal stability**

The overall mean CIS ratings (combined across all constructs and all sessions) showed good temporal stability coefficients for all session pairings (1v2, r=0.76, p,.0002; 1v3, r=0.78, p<.0001; 1v4, r=0.75, r=0.75, p<.0004; 2v3, r=0.85, p<.0001; 2v4, r=0.74, p<.0004; 3v4, r=0.83, p<.0001). Such findings indicate good temporal stability, but could also be due to strong response bias. The temporal stabilities of the individual CIS ratings were also calculated. If a response bias exists, then it would be expected that individual CIS ratings would correlate highly over time irrespective of the construct being rated. Full details of the inter-session correlations for the individual Construct Importance Scale ratings are given in Table 6.81. This analysis demonstrated great variability among the CIS ratings in terms of their temporal stability, with correlations ranging from 0.0 to 0.82 (see Table 6.81).

These data suggest that CIS ratings are not subject to any great response set effects and that temporal stability appears to be dependent upon the nature of the construct.

Table 6.80: Correlationsa between age, intellectual level and CIS scores; session 4 data.

| | AGE (n=18) | | FSIQ (n=16) | | PIQ (n=16) | | VIQ (n=16) | |
|---|---|---|---|---|---|---|---|---|
| | r | p | r | p | r | p | r | p |
| CIS1 | .20 | .43 | .04 | .89 | .09 | .75 | .01 | .99 |
| CIS2 | -.04 | .89 | -.05 | .85 | -.06 | .83 | -.05 | .86 |
| CIS3 | -.16 | .52 | -.15 | .58 | -.23 | .39 | -.02 | .95 |
| CIS4 | .31 | .21 | -.02 | .93 | -.08 | .76 | .03 | .90 |
| CIS5 | .05 | .85 | -.19 | .49 | -.21 | .44 | -.15 | .57 |
| CIS6 | .29 | .25 | .08 | .77 | .09 | .75 | .08 | .76 |
| CIS7 | .18 | .47 | -.71 | .002 | -.50 | .05 | -.66 | .01 |
| CIS8 | .11 | .67 | -.09 | .73 | -.03 | .93 | -.01 | .97 |
| CIS9 | -.07 | .78 | -.23 | .40 | -.35 | .18 | -.04 | .88 |
| CIS10 | -.48 | .04 | .05 | .85 | -.06 | .82 | .10 | .72 |
| CIS11 | .14 | .59 | .12 | .66 | -.20 | .46 | .31 | .24 |
| CIS12 | -.01 | .97 | -.33 | .21 | -.55 | .03 | -.14 | .61 |
| CIS13 | .15 | .54 | -.30 | .26 | -.19 | .48 | -.27 | .32 |
| CIS14 | .23 | .35 | -.10 | .70 | .05 | .86 | -.21 | .42 |
| CIS15 | .35 | .16 | -.12 | .65 | .10 | .70 | -.20 | .45 |

[a] Spearmans rho

Table 6.81: CIS inter-session correlations[a], epilepsy patients (n=18)

| | Session pairing | | | | | |
|---|---|---|---|---|---|---|
| CIS | 1v2 | 2v3 | 1v3 | 3v4 | 2v4 | 1v4 |
| 1 | .64* | .62* | .51 | .35 | .56 | .25 |
| 2 | .30 | .16 | -.07 | .73** | .28 | -.27 |
| 3 | .54 | .50 | .26 | .53 | .42 | .23 |
| 4 | .46 | .49 | .12 | .54 | .12 | .008 |
| 5 | .57 | .72** | .48 | .72** | .73** | .56 |
| 6 | .36 | .73** | .36 | .49 | .39 | .19 |
| 7 | -.02 | .41 | .15 | .05 | .16 | .21 |
| 8 | .14 | .61* | .41 | .56 | .40 | -.03 |
| 9 | .18 | .49 | .65* | .72** | .72 | .54 |
| 10 | .20 | .24 | .43 | .65* | .46 | .36 |
| 11 | .35 | .57 | .57 | .41 | .67* | .57 |
| 12 | -.02 | .00 | .54 | .18 | .07 | .23 |
| 13 | .53 | .61* | .50 | .80** | .58 | .34 |
| 14 | .19 | .57 | .45 | .82** | .51 | .42 |
| 15 | .24 | .84** | .38 | .71** | .76** | .55 |

[a] Spearmans rank order coefficients

CIS, Construct Importance Scale; Time intervals: 1v2=1 month; 2v3=2 months; 1v3=3 months; 3v4=3 months; 2v4=5 months; 1v4=6 months.

Note: CIS1 and CIS2 = Physical constructs
CIS3 and CIS4 = Cogntive constructs
CIS5 and CIS6 = Emotional constructs
CIS7 and CIS8 = Social constructs
CIS9 and CIS10 = Economic/employment constructs
CIS11.... CIS15 = Additional constructs (can be any of above domains)

### 6.6.b.vii **Response bias**

Analysis of variance on CIS ratings (summed over constructs) by individual patient suggests that people do vary in their use of CIS ratings (see Table 6.82 for ANOVA summary table). This may be evidence of response bias or reflect the fact that important constructs were elicited for some patients, but not for others. The ease in which constructs were elicited did vary from patient to patient and this may be reflected in the importance of those given. The existence of possible response bias was investigated further by looking at the correlation between mean CIS ratings (all constructs combined, sessions 1 to 4) with the mean repertory grid deviation score (all constructs and all elements, grids 1 to 4) (see chapter 5 for how the deviation score was calculated). It was hypothesised that if people had a response bias to using the extremity ratings on the CIS, they would also exhibit the same trait in their RG ratings. No association was seen (Spearmans, $n=18$, $r=0.01$, $p<.97$) suggesting that response bias is minimal.

Table 6.82: ANOVA summary table, CIS rating by patient

| Variable | R-Square | F | p |
|---|---|---|---|
| CIS1 | 0.188 | 3.40 | .0001 |
| CIS2 | 0.371 | 8.65 | .0001 |
| CIS3 | 0.298 | 6.24 | .0001 |
| CIS4 | 0.337 | 7.47 | .0001 |

Based on 18 patients with CIS data on all 4 occassions, total number of CIS ratings=268 (15 per patient, ID 35 only had 13 constructs).

# CHAPTER 7
# DISCUSSION

## 7.1 INTRODUCTION

The main purpose of this work has been to produce a QOL assessment tool specifically designed for use in patients with epilepsy. The resultant measure/questionnaire needs to be flexible enough to cope with the myriad of ways in which QOL may be compromised by the diagnosis of epilepsy yet robust enough to conform to accepted standards of reliability, validity and sensitivity. The discussion section begins with a critique of the psychometric properties of the novel method proposed (as this is the crux of the thesis) (Section 7.2). Section 7.3 discusses the structure of the method itself and the applicability of repertory grid technique to the study of QOL. Section 7.4 considers the psychometric properties of the existing and novel measures used to validate the QOLAS. The areas of importance identified by the patients in this study are discussed in section 7.5. Issues surrounding more general aspects of the study, for example, analyses performed, choice of population studied and study design are covered by section 7.6. Recommendations for further research are contained within the relevant sections.

## 7.2 PSYCHOMETRIC PROPERTIES OF QOLAS

### 7.2.a Background

A number of experimental measures were derived from the repertory grid approach employed. The aim of this critique is to determine which of these outcome measures possesses acceptable psychometric properties, specifically relating to test-retest reliability, validity and sensitivity. To recap, five global or aggregate scores of QOL are suggested: ABS, DIR, ABS6, DIR6 and ABS21 (see Chapter 5 for details). All are based on the distance between the ratings given for the elements NOW and LIKE (the Now-Like distance). Some of these measures involve ranking and some take the absolute or directional value of the Now-Like distance. These scores provide a measure of overall QOL, as defined in Chapter 1. Two theoretical questions are of interest. First, does ranking improve the sensitivity of the score; and secondly, is there any difference depending on whether the absolute or directional value is used.

In addition to global scores, the method allows calculation of profile scores (covering the five areas assessed namely: physical functioning, cognitive status, emotional status, social functioning and economic/employment status). Two methods for calculating these profile scores are compared. Aggregate and profile scores will be discussed separately throughout the chapter.

7.2.b **Test-Retest Reliability**

The acceptability of the reliability coefficients of the RG-based measures will be discussed in line with two suggestions: first, that the degree of acceptability will vary according to the purpose to which the measure is to be ultimately used. Ware et al. (1981) suggest that for individual comparisons a coefficient of 0.9 is needed while for group comparisons a coefficient in excess of 0.5 is sufficient. Secondly, McDowell and Newell (1987) suggest that it is useful to view psychometric data in relation to figures normally reported, for example the data provided by existing tests. It also needs to be remembered that temporal stability is only one facet of a measure. An acceptable measure (in terms of psychometric validity) needs to demonstrate a combination of adequate stability, validity and sensitivity. It is possible, for example, for a measure to demonstrate high temporal stability, yet be insensitive to change. In addition, QOL by its nature is a changing phenomenon and this needs to be borne in mind when deciding on acceptable levels of temporal stability. One would not expect as high a degree of temporal stability when assessing QOL on two occasions as when measuring height or blood pressure. Fransella and Bannister (1977) state that 'the overall aim is surely not to produce stable measures - stability or instability exist in what is measured, not in the measure. Our concern is, as Mair (1964) put it, to assess predictable stability and predictable change'.

In interpreting the findings relating to the reliability of the QOLAS it is interesting to note that in a review of a small sample of measures that were derived from repertory grids (but differ from those presented here) correlation coefficients ranging from 0.30 to 0.98 were found (Fransella and Bannister, 1977). The authors recommend that the

reliability of a grid must be examined in relation to the form of that particular grid.

### 7.2.b.i Aggregate Measures

Initial assessment of temporal stability was made by looking at the test-retest correlations of scores obtained on two occasions with a 1 month interval between completion of the QOLAS. Wide variation in temporal stability was evident across the aggregate measures at this time interval. The two non-ranked measures (ABS, DIR) demonstrated high temporal stability (with correlations of .77 and .72 respectively) across this time interval which can be viewed as supporting evidence of acceptable stability/reproducibility of these scores. Similar degrees of correlation have been considered acceptable by the developers of existing measures of QOL. For example, the sub-scales of the NHP were shown to have test-retest correlations at a one month interval ranging from 0.44 to 0.85, while the SIP category and overall scores have demonstrated test-retest correlations (24 hour) ranging from 0.75 to 0.92.

The ranked aggregate measures (ABS6, DIR6 and ABS21) generally demonstrated lower test-retest correlations than the non-ranked measures (ABS, DIR), although there was variation within the ranked measures. ABS21 and DIR6 showed similar, moderate stability coefficients at a 1 month interval (with correlations of 0.44 and 0.40 respectively). These are lower than would normally be considered acceptable, but are not dissimilar to those reported for the physical and social function indexes of the MHIQ (1 week interval, correlations of 0.53 and 0.48 respectively). The only measure not to demonstrate a reasonable degree of stability was ABS6 (with a 1 month test-retest correlation of 0.15). The discrepancy in performance of ABS6 and DIR6 is interesting as these are similar measures (both ranked, Now-Like distances), the only difference being that DIR6 takes the direction of the Now-Like discrepancy into account. It thus appears that whether or not the direction of the discrepancy between the rating a person gives to their life NOW and how they would LIKE to be, fundamentally alters the nature of the outcome measure. While

of theoretical interest, in practice this is likely to have little consequence as the majority of people rate their life NOW as worse than the ideal of how they would LIKE to be. There were only a minority of people who stated that they would LIKE to be worse off than they actually are (NOW).

The temporal stability of these measures was further examined by looking at the variability in test-retest correlations across the 6 months of the study, comparing all session pairings (for example S1vS2, S2vS3 etc). This was done in order to provide data on the temporal stability of the measures at a variety of time intervals. It seems that the choice of time interval for the purpose of establishing temporal stability is fairly arbitrary. An examination of the intervals used by existing measures show intervals ranging from 24 hours (SIP, LASA) to 8 weeks (NHP). As discussed in Chapter 3 the choice of time interval is a critical factor. Too long an interval and intervening circumstances may have altered a persons situation resulting in lower stability coefficients, while too short an interval may result in the person remembering their previous responses resulting in an erroneously high test-retest correlation. A striking difference emerged between the ranked and non-ranked measures with the former showing greater variability. Due to the varying time intervals between assessments a certain degree of variability would be expected. The lack of variation seen in the non-ranked outcome measures (ABS, DIR) raises the possibility of a response bias existing in these measures. While it is difficult to definitively differentiate between high temporal stability and response bias, an evaluation of the relationship between the stability and the sensitivity of these measures should provide some evidence to support or repudiate the existence of response bias. Any measure which is subject to a strong response bias is likely to be insensitive to change.

In addition, it was hypothesised that lower correlations would be seen for session pairings with a longer test-retest interval (for example S1vS4 equals a 6 month interval between assessments, while S1vS3 is an interval of 3 months). If the measures supported this hypothesis (that is the measures

behaved as expected) then this would provide further evidence of temporal stability. This hypothesis was not supported, with no apparent trends being seen. There are, however, at least two confounding factors which may explain this finding: repeat completions of the questionnaire and actual change. In relation to repeat administrations, the varying time intervals will also differ with regard to the number of times the questionnaire has been completed. For example, the test-retest correlation between session 1 and session 4 relates to a 6 month period, but it will be the fourth occasion on which the patient will have completed the questionnaire. This could explain, for example, differences in correlations seen for S1vS3 and S3vS4, both intervals of 3 months. Session 1 to Session 3 is a 3 month interval, but the questionnaire would have also been completed at session 2. However, between sessions 3 and 4 no further questionnaires were completed.

The second explanation proposes that actual changes in QOL may have occurred during the study and that these will influence the questionnaire measures and hence the test-retest correlations. In theory, these changes could have occurred at any time in the study and thus their influence on the test-retest correlations would be random. It is unrealistic to hypothesis that no change in QOL would be seen between sessions 2 and 3 (an interval of 3 months) while changes would be expected between sessions 1 and 4 (an interval of 6 months).

Finally, a third type of analysis was performed to strengthen the data relating to the temporal stability of these measures. This involved attempts to tease out the effects of life events and was conducted in a sub-sample of the population. Patients were categorised according to whether or not they had reported a significant life event(s) during the course of the study. It was hypothesised that higher temporal stability coefficients would be seen in a stable population (ie no life events having occurred) than in a population in which some changes had been reported (total group). This hypothesis was supported in part. The 1 month test-retest correlations were higher for the no life event group as compared to the total group for four out of the five

aggregate measures. The temporal stability of ABS rose from 0.77 to 0.89; DIR rose from 0.72 to 0.89; ABS6 rose from 0.15 to 0.40 and ABS21 rose from 0.44 to 0.71. Interestingly, the temporal stability of DIR6 dropped from 0.40 to 0.20.

Comparisons were also made between a group of patients reporting life events (a sub-group of the total group) and those not reporting a life event. In general, the test-retest correlations were lower for the former (as would be hypothesised), but direct comparisons across the various session pairings is difficult due to the timing of the life event (patients were included in the life event group if they had reported a life event at any time during the study; for some this may have occurred between sessions 1 and 2, for others it might have been between sessions 2 and 3 or 3 and 4).

In summary, the available evidence suggests that four of the five aggregate measures derived from the QOLAS (ABS, DIR, ABS21, ABS6) may possess acceptable levels of temporal stability. The temporal stability of DIR6 is questioned in view of the lower correlations being seen in a stable population (the no life event group).

### 7.2.b.ii **Profile Measures**

Profile scores were calculated by two different methods (denoted by Method 1 and Method 2 throughout), the performance of which will be compared and contrasted in the discussion. These measures were subjected to the same testing methods as the aggregate scores namely: examination of 1 month test-retest correlations; comparison of correlations for all inter-session pairings and an examination of stability in a stable population (no life event group).

High test-retest correlations for all profile measures (both Method 1 and Method 2) were seen at an interval of one month (Method 1, range=0.49 to 0.76; Method 2, range=0.53 to 0.75). These values are similar to those seen for corresponding sub-scales of the NHP (those considered to cover similar dimensions include: emotional reactions, r=0.80; energy, r=0.77; paid employment, Cramers C=0.86; social life, Cramer's C=0.59). For example, the test-retest correlation for

the NHP social life scale is 0.59 which compares with the QOL social profile score (method 1, r=0.69; method 2, r=0.59).

When the correlations across all session pairings were examined, little variation was evident, although slightly more variation was evident for the profile scores calculated by method 2 (method 1 range=0.53 to 0.79; method 2, range=0.25 to 0.75). This lack of any trend in relation to increasing time intervals in contrary to expectations and the possible reasons for this have been discussed in relation to the aggregate measures (confounding factors of repeat administrations and actual change). These explanations also hold for the profile measures.

The majority of 1 month test-retest correlations for the profile scores (methods 1 and 2) increased when re-calculated in a sub-group of patients who reported no life events during the course of the study. The one exception was the physical profile score (method 2) where the correlation dropped from 0.53 to 0.43. There is no logical explanation for this finding and it is therefore assumed to be due to a statistical artefact.

In summary, there appears to be little difference between the two methods of calculating the profile scores in terms of temporal stability, with all profile scores showing an acceptable degree of temporal stability.

7.2.b.iii **Suggestions for further work**

1 The stability of the group is important in evaluating test-retest reliability. Higher correlations were seen in the no life event group, however, the group number was small and a similar analysis in a larger group is recommended.

2 Due to the changing nature of QOL, it would be of value to assess temporal stability using a shorter test-retest interval, for example, 24 hours or 1 week. This would reduce the possibility of actual change occurring.

### 7.2.c Sensitivity

There are two basic types of sensitivity which are relevant to a QOL instrument: 1) the ability of a instrument to measure the impact of illness (or another variable) on QOL and thus differentiate between populations with varying degrees of illness. The term 'sensitivity' is used in this discussion to relate to this ability; 2) the ability of an instrument to detect change over time and this is referred to as 'responsiveness'. The sensitivity/responsiveness of the RG-based measures was addressed by three different types of analyses, varying in the degree of change in QOL expected and thus in the degree and type of sensitivity/responsiveness required by the outcome measures. To recap, these were: 1) examination of pre- and post-operative scores in trigeminal neuralgia group; 2) ability to differentiate scores of life event and no life event groups and; 3) correlation of change in QOL scores with change in life event scores. Methods 1 and 3 provide some evidence of the responsiveness of the measure (that is ability to detect change over time) while method 2 provides evidence of the sensitivity of the measure in relation to its ability to discriminate between different groups (this is similar to discriminant validity).

#### 7.2.c.i Aggregate Measures

Before discussing the sensitivity/responsiveness of the aggregate measures in detail, it should be noted that the analysis involving the trigeminal patients only provides information relating to three of the five aggregate measures (ABS, ABS6 and ABS21). The reason for this is that the directional measures (DIR and DIR6) only differ from the absolute measures (ABS, ABS6) when a patient rates how they would like to be (LIKE) as worse that how they are now (NOW). This situation did not occur in any of the trigeminal neuralgia group and therefore the absolute and directional aggregate measures were identical.

A significant reduction in the aggregate measures based on absolute Now-Like discrepancies (ABS, ABS6, ABS21) was seen in patients who had been successfully operated on for trigeminal neuralgia. In contrast, no change in scores was

evident for the small group (only three patients) who remained in pain and discomfort following the operation. This suggests that these measures are sensitive in detecting changes over time, due to medical intervention, in QOL.

Published data on the sensitivity of existing QOL measures do not always include evidence of the responsiveness to change of the instrument. Examples of situations in which it has been assessed include before and after hip replacement operations (SIP, Bergner et al., 1981) and response to change following treatment in physiotherapy outpatients (MHIQ, Chambers, 1988). It could be argued that this operation (for pain relief in trigeminal neuralgia patients) produces a dramatic change in QOL and that a measure would need to be extremely insensitive not to detect such a change. Before operation patients are in extreme pain, often unable to work or pursue their hobbies/interests, prone to depression and finding it difficult to eat, talk or socialise. The change following operation is often striking with the patient able to return to their old lifestyle in freedom from pain. Patients often spontaneously report that their QOL has improved immensely. One response to this would be that it is necessary to establish the sensitivity of a novel method in a situation where an obvious and expected change of QOL occurs. This can then be supported by further studies to establish the degree of sensitivity of the measure. If this preliminary stage is not performed and a study conducted in circumstances in which the expected change of QOL may not be very large, then interpretation of negative findings would be difficult. It may be the case that the measure used is insensitive or it could be that no change in QOL occurred. In this situation, the sensitivity of the measure can neither be supported or rejected.

Further evidence of the sensitivity of the measures used in this study, particularly in relation to the ability to differentiate groups of subjects, is supplied by an analysis of the influence of life events on the QOL of patients with epilepsy. Two of the five aggregate measures (ABS21, ABS6) successfully discriminated the QOL scores of a group of patients who had experienced a life event during the study

from those who has not, the hypothesis being that a greater change in QOL scores would be seen in the life event group. This analysis was conducted in a sub-group of the epilepsy population (the first 19 participants) who were simply asked on each occasion that QOLAS was completed 'has any major life event occurred since your last visit'. There are a number of problems in using this type of life events analysis as evidence of sensitivity: 1) a questionable link between life events and QOL; 2) small group numbers and 3) the crude nature of the life event assessment.

The latter issue (crudeness of the approach to assessing life events) was addressed by instigating the use of a formal life events scale (Life Events Schedule, Sarason et al, 1978) into the next phase of the project (Study 2). An analysis of these data, however, revealed no correlation between changes in life event scores and changes in QOL. This may raise questions about the sensitivity of the method. It is felt, however, that this lack of association is more likely to be related to factors connected to the life event questionnaire and the population studied than to the insensitivity of the QOL measures. An examination of the mean LES scores shows low scores with little variation in the data (see Appendix 31). It would be expected, and indeed hoped, that a QOL measure would not be over-sensitive to small changes in everyday circumstances.

It is probable that methodological variations between the two methods of assessing life events may account for differences in the usefulness of the findings in determining the sensitivity of the measures. Method A simply involved asking the patient if anything major had happened to them during the study. Using this approach, it is likely that only major changes would spring to mind and be reported. In contrast, Method B involved the completion of a formal questionnaire and this approach may encourage smaller changes in life events to be reported than is likely with Method A. This may explain why differences between life event and no life event groups as assessed by Method A, while life event data collected using Method B did not prove to be of value in establishing the sensitivity of the QOLAS. This type of

approach (group discrimination) to assessing sensitivity has been widely used, for example, the NHP has been demonstrated to be sensitive to detecting differences between 'well' and 'ill' populations. Due to lack of access to a variety of different patient groups, life events was used in the epilepsy patient group as a means of artificially creating groups in which differences in QOL scores would be expected. While the use of life events as a grouping factor provided a starting point, further evidence of the ability of the measure to distinguish groups of patients with varying degrees of illness would be useful.

7.2.c.ii **Profile Measures**

Evidence for the sensitivity/responsiveness of the profile measures is scanty and further work in this area is recommended as a priority. In relation to responsiveness to change, four of the five profile scores calculated by method 2 (PHYS2, COG2, EMOT2, SOC2) successfully discriminated between pre- and post-operative scores in the trigeminal neuralgia group, providing some evidence of the responsiveness of these measures. It is interesting that no change was seen for the profile score assessing economic/employment situation (WORK2). It is difficult to find a logical explanation for this finding, although it is likely to be related to the individual nature of this small, highly selected group of patients (basic details of these patients can be found in Chapter 6, Table 6.3). Thus, it is possible that this aspect of life may not have been greatly affected by the illness for a variety of reasons specific to the group studied (for example, being retired, being financially secure, not being worried about losing job through illness). Method 1 profile scores were not calculated for this group of patients and so the sensitivity of these measures cannot be determined.

In the epilepsy group, the profile scores (methods 1 and 2) showed no association with life event scale scores, suggesting that these measures are not responsive to minor changes in life situation. With regard to their ability to discriminate between groups (defined here as sensitivity), none of the profile scores (method 1 or method 2) proved

sensitive to differentiating between patients with epilepsy who had experienced a life event during the study from those who did not. This is in contrast to the ability shown by several of the aggregate measures to do so, and may be due to the specific nature of profile measures. A life event may impact on overall QOL (as assessed by the aggregate measures), but the effect on profile scores will be dependent upon the type of life event that has occurred. Performing group analyses may obscure any individual differences.

Alternatively, the profiles measures may not be sensitive to detecting group differences. Further work is needed to establish the ability of the profile measures to differentiate among groups with differing characteristics.

7.2.c.iii **Recommendations for further work: Sensitivity**

1 Need to establish sensitivity/responsiveness of outcome measures (both aggregate and profile), particularly in relation to patients with epilepsy. Suggestions for assessing responsiveness to change include comparisons before and after surgery (complete relief of seizures), before and after medication changes, before and after psychological therapy. Sensitivity (ability to differentiate groups) could be tested in the following: severe/less severe groups of patients; well controlled vs poorly controlled; employed vs unemployed; institutionalised vs community groups.

2 Further evidence, in particular, is needed to establish the sensitivity of the economic/employment profile score.

3 Further data is needed to establish the best method for calculation of profile scores (method 1 versus method 2). No comparison of the sensitivity of these methods was possible in this study (see Table 7.1).

7.2.d **Validity**

There are a number of types of validity: content validity (including face validity), criterion (or concurrent validity) and construct validity (includes convergent and divergent validity). These have been discussed in detail in Chapter 3.

### 7.2.d.i Content validity

Face validity refers to the extent to which a measure appears to assess what it is intended to. This is usually made by a subjective judgement. The individual nature of QOLAS implies an inherent face validity and this is supported by the finding that patients often spontaneously reported pleasure at being asked about concerns which were of importance and relevance to them.

The content validity of the QOLAS has been more formally addressed by an analysis of the responses to the Construct Importance Scale. This scale asked respondents to rate how important they felt each item included in the questionnaire was to their overall quality of life. In more than 75% of cases patients rated items as 'very' or 'extremely' important. Only 2% of constructs were rated as having no importance to the individuals quality of life. This indicates that items of importance to the individual are being elicited during the interview and are thus included in the questionnaire. In scales in which the selection of items for inclusion in the scale has been based on interviews with professionals, patients and carers (for example, the SIP and NHP), the content validity is usually assessed by using factor analytic techniques to determine which items cluster together and provide useful information about some underlying trait. Due to the individualistic approach and the small number of items used in the technique (QOLAS contains 10 items (or constructs) compared to 136 for the SIP and 45 for the NHP) this type of analysis was not statistically feasible.

The finding that the QOLAS appears to tap areas of importance to the individual does not necessarily mean, however, that all areas of importance are being included in the assessment or indeed that the most important areas are all included. The issue of the choice of constructs to be included in the questionnaire and how they are obtained is discussed in more detail later (see Section 7.3, this chapter).

### 7.2.d.ii **Criterion Validity**

Criterion validity can only be assessed in situations where a 'gold standard' exists against which to compare a new measure. No such standard exists for the measurement of QOL in patients with epilepsy and thus it was not possible to assess this type of validity.

### 7.2.d.iii **Construct Validity**

In the absence of a 'gold standard', the validity of a measure can be determined through establishing and testing a series of hypotheses which relate to how the measure is expected to behave in certain situations. The greater the number of hypotheses that are confirmed, the stronger the evidence for validity. The extent to which a measure correlates with other measures which assess similar or different underlying traits is often used to determine the validity of a measure. It would be expected that measures addressing the same underlying traits would be more closely correlated than measures assessing different traits. This hypothesis forms the basis of the multitrait, multimethod test of validity proposed by Campbell and Fiske (1959) which has been used to assess the validity of the RG-based measures of QOL. This approach was also used by Andrews and Crandall (1976) to assess the validity of the Cantril ladder.

It is important to remember when interpreting construct validity data that the absence of a gold standard makes the issue of establishing validity a complex one. Lack of correlation with the chosen, existing measures may indicate poor validity; alternatively it may mean that the new measure is reflecting more closely the desired trait (for example, quality of life) than the chosen proxy measure. Also, if too high a correlation is seen between the new and existing measures, this invalidates the need for a new measure.

<u>Aggregate Measures</u>

Due to the large number of correlations being made and the small group number, it was considered advisable to apply a Bonferroni correction to determine the acceptable level of significance to be adopted. None of the hypothesised correlations reached these strict levels of significance,

nonetheless the magnitude and ordering of the correlations are of interest and have some bearing on the validity of the proposed measures. The lack of statistical significance is likely to be a reflection of the small n. Two of the ranked aggregate measures (ABS6, ABS21) showed high correlations (in excess of 0.50) with the response to a independent rating by the patient regarding their satisfaction with life in general, and these were higher than the correlations seen with any other measure (assessing differing traits) (see Chapter 6, Table 6.11 for details). DIR6 also follows the expected trend (higher correlation with rating given to satisfaction with life in general), although the correlation between DIR6 and overall life satisfaction is weaker (r=0.33, Table 6.11). This suggests an acceptable degree of validity for these measures. The validity of the non-ranked measures (ABS, DIR) is more questionable. Although reasonable correlations were evident with the rating of satisfaction with life in general (ABS, r=0.33; DIR, r=0.32: Table 6.11), these measures also showed moderate correlations with several other measures in the matrix. For example, ABS and DIR showed higher correlations with measures of satisfaction with physical ability, cognitive ability, social life and finances than with the measure of overall satisfaction with life (see Chapter 6, Table 6.11). This is contrary to the MTMM hypothesis and thus raises questions concerning the validity of these measures.

It is interesting to note that although the analysis employed two independent measures of global QOL (a global rating of satisfaction with life in general and the total score from the SIP), none of the aggregate measures showed notable correlations with the SIP total score. The conclusion of an acceptable validity for three of the five aggregate measures (ABS6, ABS21 and DIR6) is based solely on evidence of high correlations with the global rating of satisfaction with QOL. This discrepancy could raise doubts about accepting the validity of these measures or alternatively questions the use of the SIP total disability score as a validator. That the latter is likely is supported by the finding of low correlations between the SIP total score and the global rating of satisfaction with life in general (see Chapter 6, Table

6.56). The choice of independent measures used as validators is discussed more fully in Section 7.4.

In addition, the theoretical basis of the SIP and the QOLAS are fundamentally different. The SIP aims to assess the impact of illness on certain functions and the questions are phrased 'please tick any item which apply to you today and are related to your health'. Example items include: 'I behave nervously of restlessly' (Emotions scale) and 'I avoid having visitors' (Social interaction scale). It differs from the QOLAS in two main ways:, first, it takes no account of the importance of the items to the individual and second, it makes no attempt to assess the impact that these disabilities have on the life of the individual as perceived by that individual. In contrast, the QOLAS only includes areas of functioning considered to be important by the individual and assesses how much of a problem they perceive these to be (that is, the QOLAS assesses an individuals self-perception of the impact of disability or impaired function as opposed to the degree of disability). These differences in approach may account, at least in part, for the low correlations seen between these two measures. It was also noted that patients with long standing epilepsy often had difficulty in responding to the 'and is related to your health' aspect of the SIP. For these patients, having epilepsy was such an integral part of their lives that it was impossible for them to assess the impact of epilepsy per se on their functional abilities. Such problems in responding to this questionnaire may have implications for its validity and use in this group of patients.

Profile Measures

The multitrait multimethod matrices used for assessing the validity of the profile scores can be found in Chapter 6 (Tables 6.26 (Method 1) and 6.28 (Method 2)). The validity of the five profile scores was addressed by consideration of the correlations with one or more independent measures of physical functioning, cognitive ability, emotional status, social functioning and economic/employment situation. The matrices also contain correlations with global measures of QOL

including those derived from the repertory grid method (QOLAS). Examination of the matrices (for both methods) reveal high and often significant correlations between the profile scores and the aggregate scores of the RG-based assessment of QOL. It is likely that these are a method artefact. This is supported in part by the finding that higher and more consistent correlations are seen between the profile measures and the non-ranked aggregate measures. These, like the profile scores, are based on the calculation and summation of the Now-Like distance for each construct. These correlations will not be considered further in the discussion of the validity of individual profile scores.

To recap, two methods were used to calculate the profile scores (Method 1 and Method 2). Large differences between the two methods are not expected and, wherever possible, they are discussed co-jointly. For clarity, however, where many differences are found the two methods will be discussed individually. Bonferroni-adjusted levels of significance were adopted to compensate for the large number of correlations being made and although very few of the correlations reached statistical significance, the size and ordering of the correlations are of interest and have implications for the validity of the measure. The inability of the current study to conclusively establish validity is recognised. Further work with larger group numbers will be needed to substantiate these preliminary findings.

Physical Profile Score

**Method 1:** the physical profile score correlated poorly with the two independent measures of physical functioning (obtained from Global Rating Scale and Sickness Impact Profile), although these correlations were generally higher than those seen with measures of non-physical traits (10/12 possible correlations were lower) (see Chapter 6, Table 6.26). Higher correlations were evident with a measure of emotional state (SIP emotions dimension score) and a global assessment of QOL (SIP total score). While weak evidence, the application of the MTMM hypothesis does suggest some degree of validity. The correlation with a measure of emotional state may reflect the

fact that the physical profile score often contained a construct relating to having epilepsy for example, 'having epilepsy' or 'having fits' (48 out of 50 patients). Epilepsy is not a simple physical illness and this finding may reflect the emotional impact that having epilepsy produces in an individual.

The correlation with a global score of QOL may be due to the fact that for patients with epilepsy, their overall QOL may be greatly influenced by the state of (or their perceived satisfaction with) their epilepsy. This is in line with Maslows's hierarchy of needs (Maslow, 1970) - physical ability is a basic need and other, higher order, needs such as emotional security and self-esteem do not become important until the more basic need (in this case adequate control of seizures and hence satisfaction with physical functioning) has been achieved.

**Method 2:** the physical profile calculated by method 2 appears to behave differently to that calculated using method 1. Validity for the physical profile score (method 2) is supported by the finding of a moderate correlation with an independent measure of physical function (SIP physical dimension score, r=0.33: Chapter 6, Table 6.28), which is higher than all other correlations with measures of different traits. Unlike the method 1 score which showed similar (albeit low) correlations with the two independent measures of physical ability (see Chapter 6, Table 6.26: SIP-PHYS, r=0.29; GRS2, r=0..25), the method 2 score showed virtually no correlation with the response to the question 'how satisfied are you with your physical abilities' (r=0.03: Chapter 6, Table 6.28). In addition, the method 2 score showed no correlation to any emotional measure (as had the method 1 score). The association of the physical profile score with a global measure of QOL (SIP total score) seen for method 1 is also seen with method 2, further supporting the suggestion that physical ability is a overriding consideration in an individuals assessment of their overall QOL.

**Method 1/Method 2 differences**

The differences in performance of the physical profile scores

depending on which method was used to calculate them while not of major significance are nonetheless of interest. What are the basic differences in calculation and how would these be expected to influence performance?

The methods basically differ in the way in which the constructs were classified as either physical, cognitive, emotional, social or economic/employment related. In Method 1, three independent raters placed each construct into one or more of the five categories (physical, cognitive, emotional, social, economic/work) on two separate occasions. A category weighting score was then calculated for each construct, the maximum being 6 (the three raters placing the construct in that particular category on both occasions) and the lowest being 0 (no rater placing the construct in that category on either occasion). The profile score for each category was then calculated by summing the rating (Now-Like distance) given for all constructs with a weighting for that category. For example, 'having fits' may have a physical weighting of 4 and a Now-Like rating of 2; 'bad back' may have a physical weighting of 6 and a Now-Like rating of 4; 'depression' may have a physical weighting of 1 and a Now-Like rating of 4. The physical profile score calculated by this method would be: (4x2)+(6x4)+(1x4)=36. This method thus allows a weak physical construct which is, for example, predominantly an emotional construct (eg. depression) to be included in the physical profile score. The association seen for method 1 between the physical profile score and a measure of emotional status may be due to the raters classifying mainly emotional constructs with some degree of physical impact. Having epilepsy may, for example, be viewed as impacting more on emotional function than physical abilities.

In contrast, method 2 consists of one rater placing the 10 constructs exclusively into one of the five categories (physical, cognitive, emotional, social, economic). Constructs are only placed in one category and the profile score calculated by summing the ratings given for those constructs within a category. For example: if 'having fits' and 'bad back' were considered physical constructs by the rater and their Now-Like ratings were 5 and 4 respectively the profile

score calculated by this method would be: (5)+(4)=9. It would be expected that this method, in which constructs are only allowed to be placed in one category, would result in profile scores that are more 'purely physical' or 'purely emotional'. This would explain the marginally higher correlation with the SIP physical dimension score seen for the method 2 physical profile score (method 2 r=0.33; method 1 r=0.29)

Cognitive Profile Score

There is some evidence to support the validity of the cognitive profile scores (both method 1 and method 2). A high correlation was seen between the cognitive profile score and response to the question 'how satisfied are you with your cognitive abilities?' (see Chapter 6, Tables 6.26 and 6.28). This correlation exceeded the stringent levels of significance adopted using Bonferroni corrections and, in line with the MTMM hypothesis, was higher than that seen with any of the other independent measures (this was the case for both methods).

In addition modest correlations with the other independent measure of cognitive status (SIP alertness behaviour score) were seen, although these were marginally higher for the profile score calculated using method 1 (method 1 r=0.44; method 2, r=0.34). Correlations with SIP alertness behaviour score, however, do not entirely support the MTMM hypothesis. Higher correlations were noted with independent measures of non-cognitive abilities, notably satisfaction with life in general (methods 1 and 2), satisfaction with finances (methods 1 and 2) and satisfaction with social life (method 2) (see Chapter 6, Tables 6.26 and 6.28 for details). A possible explanation for the lower correlations seen with the SIP alertness behaviour score is that this measure is not a sensitive validator of satisfaction with cognitive abilities. This is supported by findings of low correlations between the SIP alertness behaviour score and response to a question on general satisfaction with cognitive abilities (see Chapter 6, Table 6.56).

Emotional Profile Score

The emotional profile scores (methods 1 and 2) supported the MTMM hypothesis, displaying higher correlations with two out of the three independent measures of emotional status (satisfaction with emotional state and MACL depression scale) than with measures of different underlying traits (see Chapter 6, Tables 6.26 and 6.28). The third measure of emotional state (SIP emotions sub-scale) showed low correlations with the RG-based profile scores (method 1, r=0.17; method 2, r=0.24). These correlations were exceeded by a number of the independent measures. This raises questions concerning the appropriateness of the SIP emotions scale as a validator. This issue is discussed in more detail later in this chapter (Section 7.4).

A number of correlations between the emotional profile scores and measures of other traits are worthy of note. The emotional profile scores (both methods) showed notable correlations with measures of social functioning (satisfaction with social life) and cognitive abilities (SIP alertness behaviour) (see Chapter 6, Tables 6.26 and 6.28). These highlight one of the problems in validating profile scores: inter-area dependency. The areas for which profile scores are measured (and hence the constructs within those areas) are often not independent. For example, lack of friends may be placed in the social category and contribute to the social profile score, yet may also have emotional implications. In theory, this association between profile areas is likely to be more pronounced for method 2 scores (which are produced by placing constructs exclusively into one of the five profile areas; in contrast method 1 allows an individual constructs to contribute to more than one profile score. This last hypothesis, however, is not borne out by the data as similar degrees of association between emotional profile score and measures of social functioning and cognitive status is seen for both methods.

Social Profile Score

Two independent measures (satisfaction with social life and SIP social interaction sub-scale) were used to validate the social functioning profile scores (method 1 and 2).

**Method 1:** the validity of the social profile score calculated by method 1 as a measure of social functioning is not supported. Although this profile score showed modest correlations with the two independent measures of social functioning (response to the question 'how satisfied are you with your social life' and SIP social interaction sub-scale, these were of a similar order or lower than correlations seen with measures of emotional status (satisfaction with emotional state and MACL depression scale) (see Chapter 6, Table 6.26). In line with the MTMM hypothesis, the social profile score showed low correlations with independent measures of physical function, cognitive ability and employment/economic situation. However, the high correlations seen with measures of emotional state challenges the validity of the social profile score (method 1) as an indicator of social functioning alone. That the RG measure of social functioning showed higher correlations with latent measures of emotional state suggests that these two categories are closely identified by patients.
**Method 2:** the correlations of the social profile score calculated by method 2 with all the independent measures are generally low, ranging from 0.10 to 0.47 (and lower than those seen for method 1 social profile score) (see Chapter 6, Table 6.28). This suggests that this is a non-specific measure and questions its validity as a measure of social function. As for the method 1 social profile score, similar degrees of association are seen with independent measures of emotional state as with measures of social function. In fact, the highest correlation was seen between a measure of satisfaction with financial status. The data do not, therefore, support the validity of this measure.

Economic/Employment Profile Score

Three independent measures were used to assess the validity of the economic/employment profile score. These were responses to the questions 'how satisfied are you with your employment status' and 'how satisfied are you with your current financial situation' and the work sub-scale of the SIP. The profile scores calculated by methods 1 and 2 behaved in different ways and are discussed individually.

**Method 1:** there is some evidence to support the validity of this profile score as a measure of employment/economic status. This score correlated, as hypothesised, with two of the three independent measures (notably satisfaction with finances and SIP work sub-scale) (see Chapter 6, Table 6.26). A low correlation was seen with the third independent measure which assessed satisfaction with employment status. It thus appears that the economic/employment profile score is more likely to be influenced by financial situation than employment situation (although the two are evidently related). The nature of the population studied may provide a clue as to why this should be the case. The patients with epilepsy who took part in this study all had chronic, severe epilepsy which necessitated institutional care. The majority were employed in some aspect at the residential centre and would therefore consider themselves employed. Their financial rewards, however, were relatively low. In line with Maslow's hierarchy of needs (Maslow, 1970) it may be that certain aspects of employment (job satisfaction, responsibility, feeling of doing something worthwhile etc) only become important after lower order needs have been met (for example, adequate financial reward).

It is interesting that measures of satisfaction with cognitive abilities and emotional state correlated to a similar degree with the economic/employment profile score as did measures of employment and financial status. This finding is not unexpected as these abilities are likely to be closely linked to an individuals employment situation.

**Method 2:** the only supporting evidence for the validity of this measure was provided by a reasonable correlation with the response to the question 'how satisfied are you with your current financial situation' (see Chapter 6, Table 6.28). Higher correlations were seen between this profile score and measures of emotional state and cognitive abilities. It is concluded that further evidence is needed to support the validity of the economic/employment score calculated by method

In summary, the validity of three of the five profile measures is supported (physical, cognitive, emotional). The validity of the economic/employment profile score is partially supported, while the independence of the social profile score

is questioned. The choice of these five categories was based on theoretical considerations of the QOL concept and an examination of existing QOL measures. These may need revising in light of the validity evidence presented here.

7.2.d.iv **Recommendations for further work: Validity**

1 In view of the reliance of the MTMM approach on the interpretation of a large number of correlations, the replication of the available evidence in a larger population is strongly recommended (both for aggregate and profile measures).
2 A careful consideration of the existing and novel measures employed as validators needs to be made before any replication of these analyses are made.
3 The validity of the social and economic/employment profile scores needs to be further established.

7.2.e **Summary**

It is recognised that the psychometric data presented here are not definitive; rather they should be viewed as a starting point for further studies to corroborate or refute. A summary of the findings is given in Table 7.1 (page 338).
The available evidence, however, suggests the following (see Table 7.1):

1 There is reasonable evidence to support the test-retest reliability of the QOLAS outcome measures (aggregate and profile).
2 Sensitivity for the aggregate scores and method 2 profile scores has been reasonably established in patients with trigeminal neuralgia. Further data is needed to establish this property in patients with epilepsy.
3 In general, the data relating to validity are promising. Exceptions include three of the aggregate scores (ABS, DIR, DIR6) and the social and economic/employment profile scores for which further evidence of validity is required.
4 Overall, the ranked aggregate measures (ABS21,ABS6, DIR6) demonstrated better psychometric properties than the non-ranked (ABS, DIR). The measure of choice, based on

available evidence, is ABS21. ABS6 also performed well and with further evidence to support test-retest reliability would be considered an acceptable and useful measure of global QOL.

5 There appear to be few differences related to the method of calculating the profile scores. therefore on the basis of practicality, method 2 is proposed as the preferred option.

## 7.3 STRUCTURE OF QOLAS

During the development of the QOLAS a number of decisions had to be made concerning the methodology of the instrument, for example, what elements to use, how many constructs to include, how to present the questions etc. Although these decisions were carefully considered at the time and thought to be the most appropriate, the joint benefit of hindsight and increased experience necessitates a re-appraisal of these decisions.

### 7.3.a Choice of elements

The choice of elements was made on theoretical grounds on the assumption that QOL is a comparative phenomenon in which an individual judges their current QOL by comparison with past situations and external criteria (for example, people in their lives). At the start of the study a decision was made to use ten elements. This figure was partly arbitrary and partly based on the assumption that the analysis of the resultant grids would follow the standard procedure of principal components analysis/factor analysis (Fransella and Bannister, 1977). These statistical techniques ideally require the dataset to contain more cases (elements) than variables (constructs). As we wished to consider a number of life aspects (constructs) a relatively large number of elements were required. In the event, the grid analysis used did not follow this path and thus this number of elements are not strictly necessary.

Although much of the analysis is based simply on the Now-Like distance, it is important to incorporate ratings of more than just these two elements (as has been done in SBQOL scale, Dunbar and Stoker, 1992) in order to obtain a spread of

ratings by the individual. If someone knows they only have to rate how they are and how they would like to be then they are more likely to polarise their ratings (for example scoring all 1's (best possible QOL) for how they would like to be and 5's (worst possible QOL) for how they are now), whereas if they know they also have to rate how their best friend is and how someone with the worst possible life is then they are more likely to consider their responses to give an appropriate spread of scores.

The optimum number of elements to be used remains a subject for debate and further research is recommended to determine the minimum number of elements which provide the necessary level of information.

The psychometric data on the QOLAS relate to grids which are based on the 7 elements: NOW, BEFORE, LIKE, EXPECT, BEST FRIEND, WORST LIFE AND BEST LIFE. During the early stages of the study a number of other elements were included, but due to practical difficulties were dropped. These included 'AS YOU WERE/ARE AT 25', 'AS YOU WERE/EXPECT TO BE AT 50' AND 'AS YOU EXPECT TO BE AT 75'. It soon became apparent that these elements were highly age-dependent and they were subsequently changed to 'AS YOU WERE FIVE YEARS AGO', 'AS YOU EXPECT TO BE IN 5 YEARS TIME' AND 'AS YOU EXPECT TO BE IN 10 YEARS TIME'. The main difficulty with these was the non-concrete nature of the elements. Patients often replied 'I have no idea how I will be in 10 years time'. In addition it was felt that these elements were simply assessing their hopes for the future (as opposed to how they realistically viewed their future) and in many ways duplicating the element 'AS YOU WOULD LIKE TO BE'. A final change was made to 'MOTHER', 'FATHER' AND 'AS OTHERS SEE YOU'. A number of difficulties were also apparent with these elements. Mother and father caused problems, particularly among patients whose parents were no longer living, who found it difficult to remember what they had been like. In some instances where death of a parent was fairly recent this caused distress and an inability to recall positive aspects of their parent (due to remembering them as 'old' or 'ill'). Patients also had difficulty with the abstract nature of assessing themselves 'AS OTHER PEOPLE SEE

YOU'.

An area of interest was the stability of the elements chosen. With the exception of 'AS YOU ARE NOW' the elements were chosen to provide a framework against which it would be possible to judge an individuals current QOL. It was, therefore, considered important that people's opinions/views of these reference points remained relatively stable over time. Instability in the ratings given to the elements would make interpretation of change in QOL scores difficult as these may be due to a change in actual circumstance (NOW) or to a change in the individuals reference points (for example, viewing the worst possible life less negatively). The only elements in which some variability would be considered acceptable are NOW (actual circumstances likely to change) and LIKE (it has been stated previously that QOL can be improved by ensuring an individuals aspirations are realistic which may result in changes to their view of the 'ideal life').

An analysis of the stability of the seven elements used in the main analyses (NOW, BEFORE, LIKE, EXPECT, FRIEND, BEST LIFE, WORST LIFE) indicates that, in general, subjects were fairly stable in the ratings given to these elements over time (see Chapter 6, Table 6.37). To put the data in context, the highest variation was seen for the element WORST (variation=8.48: see Chapter 6, Table 6.38), while the maximum possible variation for a single element (summed over all ten constructs) is 53.3. However, between-element differences in relation to stability were seen and are of interest.

The most stable element was LIKE. This in not unexpected as the nature of the rating system used (no problem .... it could not be worse) may have resulted in the majority of people consistently using the lower ends of this scale when identifying the situation they would like to see themselves in. BEST, FRIEND and BEFORE are next in line in relation to stability. This fits with the hypothesis that concrete situations are likely to be more stable than hypothetical ones. It would be interesting to see if the elements that were excluded (AGE 25, AGE 50, AGE 75, 5 YEARS AGO, IN 5 YEARS TIME, IN 10 YEARS TIME, MOTHER, FATHER, AS OTHERS SEE YOU), many of which are abstract/hypothetical situations demonstrate

higher variability. This analysis was not possible due to the small numbers of patients completing grids containing these elements.

The element NOW shows quite high variability in comparison to the other elements. This is not unexpected as it is likely that people's situation will change over time and thus their ratings alter accordingly. What is a problem now, may not be in six months time. The highest variability was seen for the elements EXPECT (how you expect to be) and WORST (the worst life imaginable). This may reflect the abstract nature of these elements. Patients often reported difficulties in rating how they would expect to be and also in imagining the worst life possible. They were often reluctant to choose an actual person with the worst life imaginable (whereas no problems were encountered when choosing someone with the best possible life). In many instances, often fairly vague concepts were thought about, for example, people in the Third World, tramps/homeless people and this may have been reflected in the high variation in ratings seen for the element WORST. The higher variability seen for the elements EXPECT and WORST raises questions about their usefulness and could provide an argument for excluding these elements in order to simplify and shorten the QOLAS procedure.

### 7.3.b Construct Elicitation

A standard repertory grid technique (triadic presentation of elements) was mainly used to elicit individual constructs. This involves presenting three elements to the subject and asking them to group two together and say how they are similar yet different from the third. Where subjects had difficulty in understanding this procedure, it was simplified by presenting two elements only and asking the subject to discuss ways in which the two elements were similar and different in relation to their QOL. In all cases this procedure was preceded by a semi-structured interview in which basic information about the patient was obtained, for example, their epilepsy history, social situation, employment situation. This information proved useful in building a rapport with each patient and guiding questioning during the actual construct elicitation

procedure.

When designing a repertory grid there are a number of decisions that need to be made with regard to the constructs to be used. These include: 1) what is the scope of the research (what areas of interest); 2) should the constructs be fixed or free or a combination of both; 3) if free constructs are to be used, how should they be elicited (interview only, triadic presentation of elements, laddering) and 4) how many constructs are needed (Fransella and Bannister, 1977).

With regard to the scope of the research, it was decided that the QOLAS needed to cover five areas of functioning (physical, cognitive, emotional, social and economic/employment). This provides a standard framework for the method. The individual nature of the method is provided by allowing each patient to determine within each of these areas two specific abilities/functions that they consider important to QOL. The decision to elicit two constructs per area was based on a consideration of the time it would take to complete the QOLAS. The original grid format of the QOLAS used 10 elements and with 10 constructs this meant that the subjects would be answering 100 questions. This is similar in length of some of the longer QOL measures (for example, the SIP contains 136 items and the WPSI contains 132 items) and it was considered that to include more than ten constructs would make the procedure too lengthy, adding to the respondent burden and possibly reducing the accuracy of the data. In comparison, the NHP (a measure noted for its brevity) contains only 47 items.

The decision to limit construct elicitation to 2 items for each of the five areas needs to be questioned in view of practical experience and difficulties in eliciting constructs within some areas for some patients. For example, some patients readily elicited five or six items within the area of social function, but had great difficulty thinking of individual items within the physical or cognitive domains. It may be that for these individuals the ability of function socially is of paramount importance to their QOL, while physical and cognitive abilities are of lesser significance. This is likely to be true in cases where few difficulties are experienced within these domains. In many cases an ability

only becomes important once it has been lost. For example, we all take being able to walk for granted and if asked to define what was important to our QOL would choose higher order needs such as good relationships and being satisfied at work in preference to being able to walk. If, however, we were restricted to a wheelchair, the ability to walk may be paramount to improving our QOL. This would fit with Maslow's hierarchy of needs theory (Maslow, 1970).

Another problem with restricting the constructs to two individual items per domain is that it is difficult to know whether the two that have been elicited are the two most important to that individual. It may be incorrect to assume that the areas of most importance will be to the fore of the individual's thoughts and thus will be the first to be reported.

This has been addressed to some extent by the inclusion in the study of a Construct Importance Scale in which subjects were asked to rate how important they considered each of the constructs elicited for them. Analysis of the Construct Importance Scale, indicates that in only 2% of cases did subjects used the category 'not at all important'. This suggests that the procedure employed does elicit constructs that are important to the individual, but does not mean that all items of importance are being tapped. For example, while on average 75% of patients used the categories 'moderately important', 'very important' or 'extremely important', the last category (extremely important) was only used approximately 25% of the time. It has been suggested that the importance of elicited constructs is related to the variety of elements used during the triadic elicitation procedure (Bender, 1974). Less 'important' constructs are elicited when only one element at a time in the triad as compared with changing two elements at a time.

Another issue to be considered is whether or not to use the same constructs over time. This is related to whether or not elicited constructs are likely to be a representative and stable sample. This issue has been addressed by Hunt (1951) (quoted in Fransella and Bannister, 1977) and Fjeld and Landfield (1961). Hunt (1951) elicited constructs using the

triadic method and found that over an interval of a week, 70% of the constructs elicited on the first occasion were repeated on the second. Similarly, Fjeld and Landfield (1961) repeated Hunt's experiment with a two week interval and found a correlation of 0.80 between the first and second set of elicited constructs. It could, however, be argued that this high correlation is due to the short time intervals employed. In QOL research, it is highly likely that aspects of life considered important by an individual would change over time. It would have been interesting (and of theoretical interest) to have re-assessed all patients at the end of the 6 month study to evaluate whether or not changes in constructs (areas of importance to QOL) had occurred.

In view of these considerations, it is suggested that the QOLAS may be attempting to obtain individual items of importance at too detailed a level. For example within the physical domain there may be 5, 10 or more individual items which are considered important by the individual to their QOL and this may be the case for all five domains. Time constraints would limit any method from being able to assess this type of detail.

An alternative would be to allow individuals to state the domains of functioning they consider to be most important to QOL. This approach has been employed in the SEIQOL (McGee et al., 1991) and assumes that an individuals assessment of their satisfaction within a domain would be based on integrating their feelings about the individual items within that domain. Thus, for example when someone is asked to rate their satisfaction with their social life, they sub-consciously integrate their feelings about many aspects (for example, social life with family, social life with friends, relationships with family and friends, number of outings, satisfaction with outings) to form an overall judgement.

The current QOLAS methodology stipulates that all respondents are assessed on the five domains (physical, cognitive, emotional, social and economic/employment). These were chosen to ensure a comprehensive coverage of aspects of the individuals life and were chosen on theoretical grounds. This may, however, not be the most appropriate approach to

individualised assessments of QOL as not all the domains may be of importance to an individual. The information obtained by the QOLAS may be improved by allowing individuals to state the domains they consider important to their QOL. This approach would have a number of advantages including reducing the time taken to administer the QOLAS and increasing the individualistic nature of the procedure. If this approach was adopted it could still be used to provide information at a global and domain level to provide guidance for planning and monitoring treatment regimes at an individual level.

A potential drawback would be that it would be difficult to make between-group comparisons where the constructs (domains considered important to QOL) may not be directly comparable. This could also apply to repeated measures design where a group or groups are monitored over time (for example before and after some intervention). In these situations it would still be possible to compare aggregate QOL scores. However, if information was needed at a domain level (for example, profile scores) this would be difficult. One suggestion would be to fix the domains used. This would go against the individualistic nature of the QOLAS approach (its main strength), however, this is necessarily of lesser importance in a group comparison situation. The ability to adapt the QOLAS procedure to suit differing applications highlights the flexibility of the repertory grid approach to assessing QOL.

It is generally accepted that the way in which constructs are elicited makes little difference to the final repertory grid (Fransella and Bannister, 1977). The triadic presentation technique used in this study is one of several possible approaches. There are, however, a number of disadvantages to this technique including length (average time to elicit ten constructs was 1 hour) and non-uniformity of element presentation across subjects (not all subjects were shown the same series of triads).

An alternative approach would be to provide a checklist of items from which the subject would be asked to choose the five (for example) most important to them. This would enable some standardisation of the procedure as all subjects would

see the same checklist, yet at an individual level there would be individual differences in the items chosen. The inclusion of an 'other' category which allowed subjects to choose an item/domain not listed would ensure that the individualistic nature of the procedure was maintained. Another method would be the use of a semi-structured interview. This approach has been used by McGee et al (1991) to elicit areas of life considered important by healthy individuals and patients attending a gastrointestinal clinic. Five areas were elicited per patient and the areas chosen included: relationships, health, family, finances, happiness, work, social and leisure, living conditions, education, independence, religion and miscellaneous.

A final, important point to make is that the wording used to describe the construct needs to be as similar as possible to that provided by the individual during the construct elicitation procedure and not interpreted by the interviewer. For example if a patient differentiates the elements by saying 'A and B both have satisfying jobs whereas C does not' then the construct should be 'having a satisfying job' not interpreted by the interviewer to be 'job satisfaction'.

### 7.3.c Choice of response format

Traditionally in repertory grid research the constructs are presented as bipolar entities (for example, good memory ..... poor memory) with the extremes of the construct provided by the subject/patient. Subjects are then asked to rate themselves along this dimension. This approach was not adopted for the current project for two reasons: first, a pilot study in which this was attempted highlighted practical difficulties in eliciting both extremes for a construct and; second, it was felt that it would be more interesting to determine how patients felt their abilities impacted on their QOL, thus they were asked to rate how much of a problem they viewed each item as opposed to how they felt they were actually functioning. The World Health Organisation (1980) recognise this distinction between disability and handicap where the degree of handicap will depend upon the support available to an individual rather than absolute disability in terms of

function. It is possible for two people with the same severity of epilepsy to view their situations differently. Thus, the patient who has a lot of social support and a sympathetic employer may view their epilepsy as not much of a problem while the patient who lacks social support and is unemployed may view their epilepsy as a great problem. It could be argued that the use of a problem-orientated approach represents a negative image of the impact of epilepsy/illness. An alternative would be to ask patients to rate how satisfied they are with their functioning within each of the domains identified by them as important to QOL. It is suggested that similar findings would be expected as the difference between these two approaches is mainly semantic. An individual who views their abilities as a problem, is unlikely to record high levels of satisfaction with those abilities.

Repertory grids can be completed using a number of response formats including dichotomising, rank ordering and rating scales. The most popular method of completing grids is by rating scales (Beail, 1985).

During the study a number of response formats were utilised including two linear analogue scales (continuous and dashed) and a five-point, labelled rating scale. The latter proved the most efficient in this group of patients. Many patients had difficulties in understanding the concept of the linear analogue scales and this resulted in long response times and concerns about the accuracy of the data collected. The main reservation about using a labelled scale centred around the imposition of the experimenter's verbal labelling (and to some extent their own construct system) which is contrary to the essential nature of the QOLAS procedure which is concerned with the assessment of individual perceptions. However, it was felt that this concern was compensated for by a reduction in the time taken to complete the questionnaire, improved clarity and improved understanding of the procedure by patients. In addition, individuals are likely to interpret the labels in terms of their own construct systems and it is assumed that these interpretation will be stable over time.

A five-point scale was chosen as it was felt that this number of categories would be sufficient to allow the QOLAS to be sensitive to change. In addition, categorical scales are easy to administer, score and analyse (Clark and Fallowfield, 1986; Fayers and Jones, 1983).

In deciding on the labels to use a number of alternatives were considered based on size (no problem, slight problem, moderate problem, big problem and it could not be worse), frequency (never,rarely, sometimes, frequently, always) and a combination of size and frequency (slight, infrequent; slight frequent; moderate frequent etc). It was felt that the most appropriate and easily understood categories were those based simply on the size of problem. Basing the categories on frequency raised issues surrounding the interpretation of the impact of a problem area on QOL, for example, how to interpret the impact of the rare problem that when it does occur acutely affects the individual and their QOL. Combining size and frequency raises the problem of ordering - does a large, but infrequent problem impact more on QOL than a small, but regular one?

### 7.3.d Scoring method used

There are numerous ways of scoring repertory grids and useful reviews of the most commonly used scores and methods can be found in Fransella and Bannister (1977), Beail (1985).

Repertory grids can be scored both manually and by computer analytic techniques. One of the earliest and most widely used computer programs for the analysis of repertory grids is the INGRID program (Slater, 1964) which analyses grids into their principal components. INGRID provides information on the relationships between constructs, elements and constructs with elements and performs a principal components analysis. This program was initially developed for analysing individual grids, but Slater later developed programs capable of comparing identical grid forms (either the same grid administered to different people or to same people on different occasions), comparing more than two grids, comparing two grids with different elements or comparing two grids with different constructs (Slater, 1977).

The analysis of grids by either principal components or factor analysis is often used with little consideration as to the meaning of the outcome measures generated by the computer. The increasing availability of commercial statistical packages for use on desktop computers (for example, Statistical Package for the Social Sciences, Nie et al., 1975) has done little to halt this tendency.

Principal components analysis was used to analyse a number of grids obtained for the current study. While the analysis proved easy, interpretation of the findings proved more complicated, particularly in attempting to analyse changes over time. As one of the projected uses for this methodology is the assessment of QOL in trials of new therapies this was an important consideration. Two main concerns arose. The first, was whether or not to impose the same two principal components obtained from analysis of the first grid (Time 1) when analysing subsequent grids (Time 2, Time 3 etc) or whether to allow the principal components program to redesignate these two components. The former may miss fundamental changes in the individuals construct system and thus not be truly representative of their QOL on that occasion, while the latter makes it difficult to compare the two grids.

The second concern related to the meaning of change in the position of the element in the two-dimensional plot produced by the principal components analysis. If element A has moved in relation to element B what does this mean in terms of the individuals QOL?. These concerns resulted in the decision not to pursue principal components analysis as the preferred method of analysing the grids produced by the QOLAS procedure.

This decision is supported by Fransella and Bannister (1977) who caution against the use of complex statistical procedures to analyse grids in the absence on the part of the researcher of a clear understanding of the procedures being carried out by the computer. In addition they state: 'there can be little doubt that as grids are used more and more the variety of grid measures and scores will increase. It is therefore important that users of grids should tighten up

their thinking as to the theoretical assumptions underlying what they believe to themselves to be measuring. In our view, they can do not better than to turn to the theory from whence the grid came'.

The QOLAS scoring method presented here is founded on a sound theoretical basis and is intended to simplify the data analysis needed. Both these considerations have implications for the validity (do the scores tell us anything meaningful?) and the practicality of the method (complex scoring is likely to deter people from using the procedure routinely).

### 7.3.e Suggestions for future development of the QOLAS procedure

One of the major drawbacks of the QOLAS as described is the length of time taken to administer it. The following suggestions are made with the aim of improving the acceptability and practicality of the QOLAS. These relate to four main areas: construct elicitation (including choice and number of constructs), choice and number of elements, response format and scoring/interpretation.

1 Construct elicitation/choice of constructs: the construct elicitation procedure is lengthy and could be streamlined by the use of a semi-structured interview or checklist in place of the triadic presentation of elements procedure currently used. In addition, the number of constructs included in the repertory grid could be reduced by asking patients to specify domains of importance to quality of life (in contrast to eliciting two specific constructs within five pre-determined domains).

2 Choice of elements: the number of items in the QOLAS could be reduced (and hence time to complete ) by reducing the number the number of elements included in the repertory grid. There is an argument for including more than the elements NOW and LIKE, and this is strengthened by the findings of higher psychometric properties for outcome measures which are based on ranking procedures. Consideration of which elements to

include needs to be based on three factors: 1) theoretical basis of QOL; 2) the applicability of the elements to the population studied and 3) the stability of the element over time (this is pertinent to which elements are chosen as reference points). From a theoretical perspective the reason for including a number of elements is that QOL is seen as a comparative phenomena in which judgements are made by comparing one's current situation with external criteria, for example, one's aspirations, past abilities, peer group. On this basis it is suggested that at a minimum, the QOLAS should contain the following elements: one which refers to current situation (NOW); one which incorporates aspirations (LIKE); one which taps past abilities (BEFORE) and one which taps peer group member or relative (FRIEND). It should be noted, however, that these reference elements (with the possible exception of FRIEND) are predominantly positive situations. Consideration should also be given to the inclusion of WORST (or some similar wording) in order the gauge the negative end of the individuals construct system.

3 Response format: the five-item rating scale seems to be acceptable to patients and provides useful QOL information, thus no changes to the response format are recommended at this stage.

4 Scoring/interpretation: in order to keep the scoring and interpretation of the findings as simple as possible it is suggested that the following outcome measures be employed: ABS6 (aggregate score) and method 2 (profile scores). This suggestion is made with the proviso that additional testing be conducted to further establish the reliability, sensitivity and validity of these measures.

## 7.4 PSYCHOMETRIC PROPERTIES OF INDEPENDENT MEASURES USED TO VALIDATE QOLAS

A number of scales were used to provide evidence for the validity of the QOLAS outcome measures. These included selected scales of existing measures (SIP, MACL) and two scales designed specifically for this study. The choice of

existing measures was based on their closeness to the trait measured by QOLAS and the existence of published data relating to the psychometric properties of the scales. While it is beyond the scope of this thesis to establish the full psychometric properties of these measures when used in a population of patients with epilepsy, it is important to understand how the sub-scales chosen as validators behave in this population. The following discussion is limited to the sub-scales of the existing measures that were chosen for inclusion in the validity analysis of the QOLAS, together with a consideration of the psychometric properties of the study-specific measures

7.4.a **Sickness Impact Profile**

Four category (alertness behaviour, emotions, social interaction, work) and two dimension (physical, total) scales from the SIP were used in the QOLAS validity analysis. In the epilepsy population the SIP scores did not appear to be influenced by age, IQ or gender (see Chapter 6, Table 6.42 (age, IQ) and Appendix 33 (gender analysis)). In addition, the selected SIP scores demonstrated good test-retest reliability at an interval of 1 month with correlation coefficients ranging from 0.62 (alertness behaviour) to 0.92 (work) (see Chapter 6, Table 6.48). The validity of these SIP sub-scales, however, was poor with expected correlations only being evident for the social interaction dimension and physical category scores. The sensitivity of the SIP scales was not established in either the trigeminal neuralgia or epilepsy groups. These findings raise doubts about the validity and sensitivity of these SIP sub-scales in this population. Care needs to be taken when using these scales as evidence of validity for the QOLAS. These findings highlight the basic problem of establishing validity in the absence of a 'gold standard' and difficulties in using standardised scales in populations outside the remit of the original development work. Validators are often chosen on the basis of past performance in differing patient groups, with no re-analysis being done in the new situation in which they are to be used to validate a novel method.

It is recommended that further testing of the psychometric properties of the SIP in patients with epilepsy is urgently needed before this scale can be recommended for use in patients with chronic epilepsy.

### 7.4.b Mood Adjective Checklist: Depression Sub-Scale

The depression scale of the Mood Adjective Checklist was used as a proxy measure of emotional status. This was chosen as depression is a common emotional problem in patients with epilepsy (Robertson, 1988; Robertson, 1989) and it was thought that this would feature highly in the QOLAS emotional profile score. In this study, 18 of the 50 epilepsy patients interviewed listed depression as one of their emotional constructs (see Chapter 6, Table 6.77).

The MACL Depression scale does not show any significant correlation with age, sex or IQ in this epilepsy population (see Chapter 6, Table 6.43 (age and IQ) and Appendix 34 (gender analysis)). A moderate degree of temporal stability was seen at an interval of 1 month, although this is lower than for some of the other scales of the MACL (anxiety, fatigue, vigour) (see Chapter 6, Table 6.53). Acceptable validity has been established for this scale which demonstrated an expected correlation with response to the question 'how satisfied are you with your emotional state' (see Chapter 6, Table 6.56). In addition, it proved sensitive to changes in QOL in the trigeminal neuralgia group. Its sensitivity in patients with epilepsy has yet to be established, however, from the available evidence this scale is considered acceptable as a validator of the emotional profile measures of the QOLAS.

### 7.4.c Global Rating Scale

This scale was developed specifically to address the construct validity of the QOLAS outcome measures. To recap, it contains seven questions which ask about satisfaction with life in general, physical ability, cognitive ability, emotional state, social life, employment and current financial situation.

GRS ratings are not influenced by age and gender (see Chapter 6, Table 6.41 (age) and Appendix 32 (gender

analysis)). A number of moderate, positive correlations (around the 0.50 level) were seen between GRS ratings and IQ, particularly with performance IQ. These were most notable with regard to satisfaction with life in general, physical ability, social life, employment status and financial situation (see Chapter 6, Table 6.41). It may be that those with higher intellectual abilities are functioning at a better level within these domains and are thus more satisfied.

With regard to temporal stability, six of the GRS ratings demonstrated reasonable stability at a 1 month interval, with test-retest correlations ranging from 0.47 to 0.75 (see Chapter 6, Table 6.45). A notable exception was satisfaction with life in general which showed very poor stability at this time interval (r=0.18). It is interesting that this same scale does not have demonstrable validity (showing a low correlation with another measure of global QOL, namely the total disability score of the SIP: see Chapter 6, Table 6.56). This suggests that assessment of an individuals overall QOL needs to consist of more than simply asking them 'how satisfied are you with your QOL today'.

Acceptable levels of validity were seen for four GRS items (satisfaction with physical ability, satisfaction with cognitive status, satisfaction with emotions and satisfaction with social functioning). Further data is needed to support the validity of the satisfaction with employment and satisfaction with work items.

Some evidence of the sensitivity of this scale is provided by the ability by some of the GRS ratings to discriminate pre- and post-operative scores in the trigeminal neuralgia group. However, this evidence is not strong as when a strict level of significance is adopted (Bonferroni) only one GRS scale (satisfaction with emotional state) demonstrated a statistically significant difference. Satisfaction with life in general, physical ability and cognitive ability showed trends in the expected direction, while satisfaction with work and finances did not show any change. The sensitivity of this scale needs to be further established, particularly within an epilepsy population. .

In summary, the physical, cognitive, emotional and social

items of the GRS are considered acceptable validators of the corresponding profile scores of the QOLAS. Further work is needed to establish the validity of the life in general, employment and work items. In addition, if this scale is to be considered as a method of assessing satisfaction with various life domains in its own right (as opposed to being used to validate a more complex instrument, namely the QOLAS), further data relating to the sensitivity of this measure in patients with epilepsy is needed.

### 7.4.d Construct Importance Scale

This scale assesses the importance an individual places on the constructs elicited for them and was included as a way of providing information about the content validity of the QOLAS. This scale appears to be minimally influenced by age, IQ or gender (see Chapter 6, Table 6.80 (age, IQ) and Appendix 50 (gender analysis)). A wide variability in CIS ratings is seen at a time interval of 1 month and this appears to be dependent on the individual construct. This suggests that people vary in the importance they attach to certain constructs. This is not unexpected as some constructs will be highly important and central to an individuals construct system while others will be peripheral and their importance will vary over time. As Quine (1978) states 'a persons individual values and beliefs are not all of equal value to that person. Some are central to the meaning given to his/her life and would not be sacrificed except in extreme circumstances, whereas other beliefs/values are more peripheral and can be modified or abandoned without fundamentally altering a persons' identity'.

That the CIS ratings do not exhibit strong temporal stability does not negate their usefulness in assessing the content validity of the QOLAS. It does, however, raise issues concerning when constructs should be elicited, particularly in relation to longitudinal studies. Should a set of constructs be elicited at the start of a longitudinal study and the same set used for repeated assessments of QOL or should a new set be determined for each assessment? There are arguments for both approaches; the former allows direct comparisons to be made over time, while the latter may give a truer

representation of the patients QOL. If the former approach is adopted (as in this study) then the CIS has a useful role to play in monitoring changes in the importance of certain constructs during the course of the study.

It may be useful to incorporate the importance attached to each construct into the scoring method of the QOLAS. For example, the Now-Like difference could be weighted by the importance given to the construct. This would allow changes in importance to be incorporated into the determination of an individuals QOL. If such an approach was to be taken, it would be necessary to establish that CIS ratings are free from response bias and not affected by external variables such as age, gender and IQ. Analysis of the variability of the CIS ratings (see Chapter 6, section 6.6.b.vii) and in particularly the tendency for patients to use the extremity ratings suggests that the CIS is minimally influenced by response bias. This finding, together with the lack of correlation with age, gender and IQ suggests that this approach may a useful way of incorporating the importance attached to constructs into the outcome measures derived from the QOLAS. This is an area of interest for further work.

Due to the nature of the CIS it was not possible or appropriate to consider validity and sensitivity.

## 7.5 AREAS OF IMPORTANCE IDENTIFIED

Given the individualistic approach embraced by the QOLAS methodology it was of interest to examine the constructs elicited. A number of questions were of interest: 1) what was the degree of overlap between patients?; 2) were the constructs provided by patients in line with expectations? and; 3) to what extent were the constructs highly individualised and idiosyncratic.

The short answer is that there was a high degree of overlap between patients, that the constructs were generally in agreement with what would be expected from a knowledge of the impact of epilepsy on psychosocial functioning and that while some idiosyncratic constructs were elicited, these were in the minority. The remainder of this section will briefly review the areas of most concern to this group of patients

with epilepsy, together with some of the interesting idiosyncratic responses.

Having epilepsy was the most commonly elicited construct for any category being given by 48 out of the 50 patients interviewed for the study. This highlights the major impact that the diagnosis of epilepsy has on an individuals QOL. Within the physical domain, the next most common construct dealt with general physical abilities. This included some specific physical abilities, for example, being able to walk or not being handicapped. These tended to be provided by a small number of patients who had a concomitant physical disability. Fatigue and tiredness was also a common area of concern, with sleep problems and epilepsy-associated incontinence being highlighted by several patients. Individualistic physical constructs (generally given by only one patient) included arthritis, catarrh, spasticity, chest pains, diabetes, head pains, angina, back trouble, dizziness, speech and having an illness. In these patients, the constant nature of these additional physical problems meant that they were often viewed as being more problematic than the persons' epilepsy.

Elicitation of constructs within the cognitive domain proved a difficult task and was not achieved in every patient. This was mainly due to difficulties in defining 'cognition' to patients. The most commonly reported areas were memory, concentration and mental speed. The finding that memory was provided by 76% of patients is not unexpected and is in line with the increasing recognition that epilepsy (and its treatment) often adversely affects memory processes (Trimble and Thompson, 1981; Thompson and Trimble, 1982b). Other constructs that were elicited were concerned with education, qualifications and literacy skills. People with epilepsy, particularly of early onset, often miss a great deal of schooling or perform less well academically than their peers (Stores, 1978; Vining, 1989). It is interesting that this lack of educational opportunity should still be considered important far into adult life (mean age of group 44.4 years, range=20-68). Having intelligence and being able to learn new things were also considered important to QOL.

A wide range of constructs were elicited within the emotional domain. The most common areas were anger/aggression, depression, frustration, anxiety and being happy and able to enjoy life. Feelings of anger and aggression were reported by 60% of patients who felt that the ability to control these feelings was important to their QOL. Other constructs provided by several patients included confidence, being in control of life, boredom, having a sense of achievement, being caring, shyness and having courage. A number of individual (provided by one person only) constructs are of interest including being pitied, being able to trust others, being realistic, having status and being able to fulfil.

Independence, social life, having close friends, loneliness and family relationships were the most commonly reported constructs within the social functioning domain, being provided by at least 32% of patients. The 'social life' construct encompasses a number of more specific items relating to social life, for example, being invited to visit people, being able to go out alone and being able to go out when you want to. These are likely to reflect the fact that the population studied were in residential care and may not be applicable to patients with epilepsy who live in the community. Other constructs worthy of note include: being able to travel/take holidays, being useful/keeping busy, having own home and being able to have children/having contact with children.

The economic/employment domain seems to centre around finances as 'lack of money' was provided as a construct by 86% of patients. This was followed by 'being in work' (32%). More specific aspects of employment were elicited from a number of patients including job satisfaction, having an interesting and enjoyable job, using your skills at work, having a 'real' job and having a well-paid job. Some of these findings are interesting in view of the literature on under-employment of people with epilepsy (Dodrill 1980b; Sillanpaa, 1983). Being financially independent, fear of losing job, trouble with employer, having enough money to save and having enough money to keep in fashion were some of the more individualistic constructs. The economic/employment domain is likely to be

highly influenced by the nature of the population studied. As mentioned previously, the majority were in residential care and were employed at the residential centre. While this kept them occupied during the day and provided some work experience, it is apparent that a number did not view this as a 'real' job.

Only a small number of constructs were elicited which did not fit easily into the domains identified (physical, cognitive, emotional, social, economic/employment). Examples include politeness (possibly a social construct), being successful, having goals, doing duty, having opportunities, getting things done, having faith in God. That this number was small is probably due to the comprehensive coverage of areas of life functioning provided by the five domains chosen.

Initial impressions of a comparison of the constructs elicited from patients with epilepsy with those elicited from the trigeminal neuralgia group are of a high degree of similarity in the areas of importance given. There were, however, a number of differences which reflect the differing nature of the two populations. Within the physical domain there were obvious, illness-related differences (for example, having epilepsy in the epilepsy group and being in pain in the trigeminal neuralgia group). Very similar constructs were provided by both groups within the cognitive, emotional and social domains, although the trigeminal neuralgia group tended to provide a wider variety of constructs. This may reflect the fact that this group live in the community (and thus lead less restricted lives), in contrast to the institutional nature of the epilepsy group. Some group differences emerged for the economic/employment domain. In the epilepsy group, the main concerns were having a job and having enough money. In comparison, the trigeminal neuralgia group were more concerned with altruistic aspects of employment, for example, having a useful job, having a rewarding job or having a caring job.

In summary, it is interesting that the areas of importance to QOL provided by this group of patients with epilepsy, mirror closely many of the areas of psychosocial functioning in which patients have been shown to be at a

disadvantage when compared to the general population. For example, patients with epilepsy have been shown to experience difficulties with family relationships (overprotection, rejection), self-esteem, emotional disorders (depression, aggression), interpersonal adjustment (including marriage), social isolation, employment and financial security (Dodrill and Batzel, 1981; Levin et al., 1988).

While recent years have seen increasing attempts to define and understand the psychosocial consequences of epilepsy, little work has been done to assess the impact of these on the patients overall QOL. One of the aims of this study was to provide a measurement tool capable of providing this type of information, that is, to answer the question 'to what extent do functional difficulties in areas of importance impact on the QOL of the patient with epilepsy?'. Whether or not this aim is achieved will depend upon the performance of the QOLAS in further, more stringent tests of reliability, sensitivity and validity.

## 7.6 STUDY DESIGN: GENERAL ISSUES

There are a number of issues concerning the study design employed which need to be considered when interpreting the findings of this study. First, the highly selective nature of the population studied makes it difficult to extrapolate these findings to either patients with less severe epilepsy, other patient groups or the general population. However, it was felt that patients at the more severe end of the epilepsy spectrum are most likely to experience difficulties within a variety of life domains and a QOL instrument should be able to be used in such a population. Despite the low mean IQ of the population studied (88.6, range 67-108), very few were unable to complete the QOLAS procedure.

A longitudinal, repeated measures design was employed in order to mirror a typical drug-trial design. An initial consideration in the development of the QOLAS was to produce a QOL instrument which would be of value in evaluating the effects of existing and novel anticonvulsant agents on QOL. It was therefore considered important to know how the QOLAS would perform in these circumstances. The longitudinal nature of the

study, however, restricted the number of patients who could be entered and completed within the time limit of the study. The small group number may account for some of the inconclusive findings of the study, particularly in relation to the correlational analyses, where large group numbers are generally recommended. The assessment of the validity of a measure does not require repeat assessments and thus a one-off assessment in a larger population would be more appropriate for establishing this property. Similarly, establishing test-retest reliability only requires two assessments and, due to the changing nature of the QOL concept, it is suggested that a short time interval between assessments be employed (for example, 1 week), in contrast to the minimum 1 month period used in the current project. Establishing sensitivity (that is, ability to distinguish groups expected to vary in QOL terms) can be achieved by a one-off assessment, enabling a larger sample to be tested. However, responsiveness to change (another type of sensitivity) requires before and after treatment assessments and is likely to be a longer procedure, thus reducing the sample size obtainable.

## 7.7 INFLUENCE OF EPILEPSY VARIABLES

The differential role played by a variety of epilepsy-related factors (for example, age of onset, seizure rate, type of medication and aetiology) in the psychosocial problems experienced by some patients with epilepsy has been extensively investigated (Sillanpaa, 1983; Dodrill, 1984; Dodrill, 1986; Beran and Flanagan, 1987; Hermann et al., 1990).

This study provides limited data relating to the influence of a variety of factors of QOL measures. The findings indicate that QOL is not affected by duration of epilepsy, aetiology, having a history of status, having a family history of epilepsy, site of epileptic activity (as determined by EEG focus), seizure type (simple partial, complex partial or generalised) or whether the patient is on monotherapy or polytherapy.

Number of seizure types did not influence global QOL scores, but patients experiencing more than one seizure type having higher scores (ie. poorer QOL) on the social and emotional profile scores of the QOLAS (see Chapter 6, Table 6.69). This is in line with expectations, as having more than one seizure type equates with a more severe form of epilepsy. It is interesting that the QOLAS scores were not influenced by either seizure type or weekly seizure rate.

With regard to medication, higher doses of sodium valproate (VPA) seem to be associated with lower global QOL scores and by implication better QOL. In addition, VPA also appears to exert a positive influence on a number of profile measures, namely economic/employment situation, emotional status and social functioning. VPA is generally considered to have a minimal effect on mood (Kendrick et al., 1993). The higher QOL scores seen in the social and economic / employment domains could be linked to the effect of VPA on cognitive abilities, VPA being generally associated with minimal effects or even improvement in cognitive function (Trimble, Cull and Thompson, 1987). Another finding of interest was a detrimental effect of clobazam (CLB) on satisfaction with physical ability.

While these medication-related findings are of interest, they need to be treated with caution due to the small group numbers and the high percentage of patients on polytherapy.

This study was not structured to specifically address the issues surrounding the influence of epilepsy-related variables on QOL. The data presented are incidental to the main purpose of the study (establishing psychometric properties of a novel method of assessing QOL) and thus the findings needs to be viewed cautiously. Nevertheless, some interesting associations are noted and a more detailed examination of the influence of these variables on QOL is warranted. The findings of such research would have implications for the validity of the QOLAS, if expected differences based on epilepsy-related variables (for example, comparing high and low seizure frequency groups) were borne out by empirical testing.

## 7.8 SUMMARY

This work reflects and builds upon an important shift of emphasis within the quality of life movement, notably an increasing recognition of the role that patient perceptions have to play in the determination of feelings regarding quality of life. This increasing emphasis on the importance of producing measures which are patient-centred and which incorporate patients own perceptions of their life quality is of particular relevance in a heterogenic, chronic disease such as epilepsy. Being diagnosed as having epilepsy may impact on the life of the individual in a myriad of ways which are specific to that individual.

The novel method described represents a new approach to the assessment of QOL in patients with epilepsy. It differs from traditional QOL measures in that the assessment asks patients themselves to define what aspects of life are important to their QOL. This is in contrast to the development of other QOL measures in which the items included in the questionnaire are either proposed by the researcher or are derived from an analysis of areas of importance suggested by a range of people including health care professionals, patients and carers. This latter approach goes some of the way to including areas which may be of concern to a patient with a specific disease, but even within restricted disease groupings, individual differences (due to age, sex, personality etc) as to the important things in life are likely to be large. The inevitable outcome of such an approach is that areas of extreme importance to an individual patient may not be considered by the questionnaire and a thus a true picture of the individuals perceptions of their QOL will not be obtained. An examination of the wide variety of concerns raised by the patients in this study highlights this individual nature of QOL.

The method described takes full account of the feelings and perceptions of individual patients not only in terms of levels of functioning, but also with regard to what areas of functioning are important to QOL and are included in the assessment. In this novel method patient perceptions are of paramount importance and have been the core principle on

which the method is based.

Studies investigating QOL in the medical setting are often criticised for their lack of theoretical underpinning. Many studies have employed a restricted approach to QOL assessment using variables such as ability to return to work or psychological well-being as proxy measures of QOL. While such factors are undoubtedly components of QOL, they do not embrace the whole QOL concept. This issue has been addressed in the development of the method described in this document which is underpinned by a clear and concise working definition of QOL. In summary, QOL is viewed as an individual, multidimensional, relational phenomenon in which an individuals beliefs and expectations are of importance. This theoretical underpinning has been applied to both the content and nature of the method and the outcome measures derived.

The application of repertory grid technique as outlined by this novel method enables a structured, yet individualised approach to the assessment of QOL. This permits an objective assessment of subjective feelings to be made. Despite the subjective nature of the QOL concept, the method described appears to possess promising psychometric properties, notably reliability, sensitivity and validity. In addition, the method was highly acceptable to patients many of whom commented on their feelings of satisfaction that areas of importance to them were being discussed. Further work, however, is needed to fully establish the psychometric robustness of the method, both in larger populations and in patients with less severe epilepsy. The group studied here were a highly select group with longstanding, severe epilepsy, in many instances necessitating institutional care and this has implications for the extrapolation of the findings of this study to other populations (for example, patients with mild to moderate epilepsy, non-institutionalised groups).

An added advantage of the method is its flexibility. Although developed primarily for use in patients with epilepsy, the individual nature of the assessment means that it may be applied to virtually any illness or situation. In addition, the method provides outcome measures both at a global level (aggregate scores: ABS, ABS6, ABS21, DIR, DIR6)

and at the level of individual life domains (physical functioning, cognitive functioning, emotional status, social functioning, economic status) enabling it to be of value is a variety of situations including monitoring change over time, making group comparisons (for example comparing different treatment regimens or different illnesses) and planning and monitoring treatment protocols. Potential areas of research in which the method may prove useful include:

* the assessment of unwanted side effects of existing and novel anticonvulsants on the QOL of the patient.

* evaluations of the impact of non-pharmacological interventions aimed at improving the QOL of the patient with epilepsy, for example studying the success of social skills training or the results of surgery.

* studying the effects of epilepsy on families.

* follow-up studies after discharge from tertiary referral centres/hospital.

* identifying views/prejudices of the public/employers in order to develop programs to breakdown these barriers.

* at the treatment level, to identify for individual patients, what areas are of concern to them and to plan treatment/rehabilitation schedules accordingly. The method may also be used to monitor the success of these treatments.

In summary, the method presented provides a novel approach to the assessment of QOL in patients with epilepsy, based on individual patient perceptions. It is hoped that this patient-centred approach to the assessment of quality of life will prove of value in addressing QOL issues which are pertinent to the patient with epilepsy.

Table 7.1: Comparison of psychometric properties of QOLAS outcome measures.

| Measure | Test-retest reliability | Sensitivity TN | Sensitivity EP | Validity |
|---|---|---|---|---|
| ABS | ++ | ++ | - | - |
| DIR | ++ | nt | - | - |
| ABS6 | ++ | ++ | + | ++ |
| DIR6 | ++ | nt | - | + |
| ABS21 | ++ | ++ | + | ++ |
| Phys1 | ++ | nt | - | + |
| Phys2 | ++ | ++ | - | ++ |
| Cog1 | ++ | nt | - | ++ |
| Cog2 | ++ | ++ | - | ++ |
| Emot1 | ++ | nt | - | ++ |
| Emot2 | ++ | ++ | - | ++ |
| Soc1 | ++ | nt | - | - |
| Soc2 | ++ | ++ | - | - |
| Work1 | ++ | nt | - | ++ |
| Work2 | ++ | - | - | + |

Key: ++ supported
+ some support, but further evidence recommended
- not supported, further evidence needed
nt not tested

TN, trigeminal neuralgia group; EP, epilepsy group;
Phys1, Phys2, physical profile score method 1 or method 2; Cog, cognitive;
Emot. emotional; Soc, social; Work, economic/employment.

# CHAPTER 8

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# CHAPTER 9

# APPENDIX

## Appendix 1: Subject Information Leaflet

**QUALITY OF LIFE STUDY: SUBJECT INFORMATION SHEET**

1. AIMS

The aim of this study is to assess 'quality of life' in people with epilepsy.

2. WHAT IS 'QUALITY OF LIFE'?

Basically, 'quality of life' refers to how happy someone is with themselves and their way of life.

Many things can affect 'quality of life':

* physical factors
* emotional factors
* social factors, including relationships with family and friends
* factors related to mental or brain processes, for example,memory and concentration
* economic factors

3. HOW IS 'QUALITY OF LIFE' MEASURED?

It is measured by means of a questionnaire which has been developed at the National Hospital for Nervous Diseases.

There are 100 items to complete on the questionnaire and it generally takes between 30 and 45 minutes to do.

4. WHAT WILL TAKING PART IN THE STUDY INVOLVE?

Those taking part in this study will be asked to visit me on 5 occasions. What will happen at each visit is described below:

VISIT 1 This takes the form of an informal interview where we will discuss your background, your epilepsy (when it started, how you feel about having epilepsy etc), together with any current problems you may have. We will also discuss what things are important to you and your QOL.

The questionnaire is based on things you think are important to your QOL which arise from this interview. The interview lasts approximately 1 hour.

VISIT 2 This generally takes place 1 week after VISIT 1 and involves the completion of the 'quality of life' and other questionnaires.

Duration:- 30-45 minutes

VISIT 3 This takes place 1 MONTH after VISIT 2. Complete questionnaires

Duration:- 30-45 minutes

VISIT 4 This takes place 2 MONTHS after VISIT 3. Complete questionnaires

Duration:- 30-45 minutes

VISIT 5 This takes place 3 MONTHS after VISIT 4. Complete questionnaires

Duration:- 30-45 minutes

5. BASIC INFORMATION

My name: Anna McGuire

Where to find me: Room 5
Pearman House
Chalfont Centre

How to contact me: At Chalfont (TUES/THURS):
Telephone: 3991 ext 213/internal ext=117

In London (MON/WED/FRI):
Telephone: 01-837 3611 ext 4272

Home number: 01-995 0721

Appendix 2: Semi-structured interview used with epilepsy patients

VERSION 1
(EPILEPSY GROUP)

QUALITY OF LIFE STUDY : INITIAL INTERVIEW

Patient name _____ Number _____

Date _____ Visit No. _____ Investigator _____

FEELINGS ABOUT EPILEPSY

1. How do you feel about having epilepsy?

a) In what ways does it affect your life? (For example, employment prospects, your relationships with family and friends etc)?

b) Does having epilepsy prevent you from doing certain things that you would like to do , for example, playing certain sports, doing certain jobs, travelling by public transport?

c) Do you feel that having epilepsy is the main cause of all the things that are not right in your life at the moment?

d) How do you feel about taking medication possibly for the rest of your life?

PHYSICAL HEALTH

1. Are there any aspects of your physical health than cause you concern at the moment ?

a) Do any of the following bother you :

| | |
|---|---|
| FITS | Y/N |
| HEADACHES | Y/N |
| ACHES/PAINS | Y/N |
| FATIGUE | Y/N |
| SLEEP PROBLEMS | Y/N |
| BREATHLESSNESS | Y/N |
| SLOWNESS | Y/N |
| CLUMSINESS | Y/N |

b) Can you think of any other physical problems that you have at the moment? (Heart problems, athritis, spasticity etc) ?

c) If >2 problems reported : which of these problems worries you the most?

COGNITIVE ABILITY

1. Do you have any problems with the way your mind/brain works? For example difficulties with :

| | |
|---|---|
| MEMORY | Y/N |
| CONCENTRATION | Y/N |
| LEARNING NEW INFORMATION | Y/N |
| PROBLEM-SOLVING | Y/N |
| DECISION MAKING ABILITY | Y/N |
| DULLNESS/SLOWNESS | Y/N |

a) How do you think these problems affect you in your everyday life?

b) Do they cause problems for you at work, with friends, doing household chores, shopping, getting on with people etc?

c) If >2 problem areas reported : which of these cause you the most difficulties?

EMOTIONAL STATUS

1. Do you have any emotional difficulties at the moment?

a) Are any of the following a problem for you :

| | |
|---|---|
| DEPRESSION | Y/N |
| ANXIETY | Y/N |
| ANGER | Y/N |
| AGGRESSION | Y/N |
| FRUSTRATION | Y/N |
| MOOD CHANGES | Y/N |
| IRRITABILITY | Y/N |
| BOREDOM | Y/N |

b) Do these emotional problems affect your life in any way?

c) If >2 areas reported : which of these are the most problematic?

RELATIONSHIPS/SOCIAL FUNCTIONING

1. Do you have good relationships with members of your family? (mother, father, brother/sister )

a) If YES : what sort of problems do you have (over-protectiveness, lack of understanding, arguments etc)

b) Do you have many close friends Y/N?

c) Are you happy with your ability to form friendships or do you find it difficult to get to know people?

d) Do you have (or have you ever had) a girlfriend/boyfriend? Are you happy with this relationship? If NO : what sort of problems have you encountered?

d) What about your social life? Do you go out as often as you would like?

e) What do you do with your spare time? Do you belong to any clubs/organisations or have particular hobbies?

f) Are you happy with the way in which you spend your spare time or do you often get bored?

WORK/ECONOMICS

1. Are you working at the moment ? If NO : have you ever worked?

a) Are you happy with the job that you do at the moment?

b) Do you ever feel that you have not realised your full potential ie that you are capable of doing a better job?

c) How do you think having epilepsy affects you at work? Has it caused you any problems, for example, the attitudes of your employer and workmates, accidents at work, time off due to seizures, loss of job, rejection.

d) Do you have any financial problems at the moment ? For example :

DEBTS Y/N : DIFFICULTY PAYING RENT Y/N : DIFFICULTY PAYING BILLS Y/N

UNABLE TO BUY WANTED ITEMS Y/N : TRAVEL RESTRICTIONS Y/N

e) Is money (especially lack of it) important to you?

AREAS OF IMPORTANCE

1. What do you consider to be the most important things to you for you to be happy and satisfied with your life? (Is it work, family, health etc)

a) If you could change or improve 10 things about yourself or your life what would they be?

1. _____
2. _____
3. _____
4. _____
5. _____
6. _____
7. _____
8. _____
9. _____
10. _____

Appendix 3: Example of QOLAS rating scale used in Study 1

Please rate how much of a problem you think the following areas are for you AS YOU ARE NOW

Construct 1:_____

no problem --- --- --- --- --- --- --- --- --- --- severe problem

Construct 2:_____

severe problem --- --- --- --- --- --- --- --- --- --- no problem

Construct 3:_____

no problem --- --- --- --- --- --- --- --- --- --- severe problem

Construct 4:_____

severe problem --- --- --- --- --- --- --- --- --- --- no problem

Construct 5:_____

no problem --- --- --- --- --- --- --- --- --- --- severe problem

Construct 6:_____

severe problem --- --- --- --- --- --- --- --- --- --- no problem

Construct 7:_____

no problem --- --- --- --- --- --- --- --- --- --- severe problem

Construct 8:_____

severe problem --- --- --- --- --- --- --- --- --- --- no problem

Construct 9:_____

no problem --- --- --- --- --- --- --- --- --- --- severe problem

Construct 10_____

severe problem --- --- --- --- --- --- --- --- --- --- no problem

Appendix 4: Life events reported by Study 1 patients

| Subject Number | Life event | Study period |
|---|---|---|
| 11 | Change in drugs with increase in violent behaviour | S2 to S3 |
| 12 | Left job | S3 to S4 |
| 13 | Close friend died | S2 to S3 |
| 18 | Drug change | S2 to S3 |
| 19 | First fit in 7 years | S2 to S3 |
| 20 | Admitted to Medical Unit with hypertension and started on medication | S2 to S3 |
| | Staff report deterioration (wandering, confused) | S3 to S4 |
| 21 | Bad fit and burn to leg | S1 to S2 |
| 26 | Daughter married | S2 to S3 |
| | Moved rooms in hostel due to problems | S3 to S4 |
| 27 | Moved to independent living | S3 to S4 |
| 32 | Moved rooms in hostel | S3 to S4 |

Appendix 5: Copy of QOLAS used in Studies 2 and 3

QUALITY OF LIFE ASSESSMENT SCHEDULE : V3.0

Patient name _____ Number_____

Date _____ Grid Number _____ Investigator _____

INSTRUCTIONS

This is a QUALITY OF LIFE questionnaire. Its purpose is to determine how happy and satisfied you are with your life at this moment in time.

Earlier we discussed certain areas of your life with which you were not satisfied or which you would like to change. You will now be asked to rate how much of a problem these areas are to you now and also for various stages of your life and various people in your life.

EXAMPLE

Please rate how how much of a problem you think the following areas would be for THE QUEEN, by writing the appropriate number in the box.

KEY : 1 = Not a problem
2 = A slight problem
3 = A moderate problem
4 = A big problem
5 = It couldn't be worse

| | | |
|---|---|---|
| 1. | Headaches | |
| 2. | Opportunity to travel | |

Trust your first impressions and work quickly. Try not to spend longer than a moment or two thinking about each question.

## AS YOU ARE NOW

KEY : 1 = Not a problem
2 = A slight problem
3 = A moderate problem
4 = A big problem
5 = It couldn't be worse

| | | |
|---|---|---|
| 1. | | |
| 2. | | |
| 3. | | |
| 4. | | |
| 5. | | |
| 6. | | |
| 7. | | |
| 8. | | |
| 9. | | |
| 10. | | |
| 11. | | |
| 12. | | |
| 13. | | |
| 14. | | |
| 15. | | |

## AS YOU WERE BEFORE DEVELOPING EPILEPSY

KEY : 1 = Not a problem
2 = A slight problem
3 = A moderate problem
4 = A big problem
5 = It couldn't be worse

| | | |
|---|---|---|
| 1. | | |
| 2. | | |
| 3. | | |
| 4. | | |
| 5. | | |
| 6. | | |
| 7. | | |
| 8. | | |
| 9. | | |
| 10. | | |
| 11. | | |
| 12. | | |
| 13. | | |
| 14. | | |
| 15. | | |

## AS YOU WOULD LIKE TO BE

KEY : 1 = Not a problem
2 = A slight problem
3 = A moderate problem
4 = A big problem
5 = It couldn't be worse

| | | |
|---|---|---|
| 1. | | |
| 2. | | |
| 3. | | |
| 4. | | |
| 5. | | |
| 6. | | |
| 7. | | |
| 8. | | |
| 9. | | |
| 10. | | |
| 11. | | |
| 12. | | |
| 13. | | |
| 14. | | |
| 15. | | |

AS YOU EXPECT TO BE AFTER TREATMENT

KEY : 1 = Not a problem
2 = A slight problem
3 = A moderate problem
4 = A big problem
5 = It couldn't be worse

| | | |
|---|---|---|
| 1. | | |
| 2. | | |
| 3. | | |
| 4. | | |
| 5. | | |
| 6. | | |
| 7. | | |
| 8. | | |
| 9. | | |
| 10. | | |
| 11. | | |
| 12. | | |
| 13. | | |
| 14. | | |
| 15. | | |

YOUR MOTHER

KEY : 1 = Not a problem
2 = A slight problem
3 = A moderate problem
4 = A big problem
5 = It couldn't be worse

| | | |
|---|---|---|
| 1. | | |
| 2. | | |
| 3. | | |
| 4. | | |
| 5. | | |
| 6. | | |
| 7. | | |
| 8. | | |
| 9. | | |
| 10. | | |
| ▸▸ 11. | | |
| 12. | | |
| 13. | | |
| 14. | | |
| 15. | | |

## YOUR FATHER

KEY : 1 = Not a problem
2 = A slight problem
3 = A moderate problem
4 = A big problem
5 = It couldn't be worse

| | | |
|---|---|---|
| 1. | | |
| 2. | | |
| 3. | | |
| 4. | | |
| 5. | | |
| 6. | | |
| 7. | | |
| 8. | | |
| 9. | | |
| 10. | | |
| 11. | | |
| 12. | | |
| 13. | | |
| 14. | | |
| 15. | | |

## AS OTHERS SEE YOU

KEY : 1 = Not a problem
2 = A slight problem
3 = A moderate problem
4 = A big problem
5 = It couldn't be worse

| | | |
|---|---|---|
| 1. | | |
| 2. | | |
| 3. | | |
| 4. | | |
| 5. | | |
| 6. | | |
| 7. | | |
| 8. | | |
| 9. | | |
| 10. | | |
| 11. | | |
| 12. | | |
| 13. | | |
| 14. | | |
| 15. | | |

## YOUR CLOSEST FRIEND

KEY : 1 = Not a problem
2 = A slight problem
3 = A moderate problem
4 = A big problem
5 = It couldn't be worse

| | | |
|---|---|---|
| 1. | | |
| 2. | | |
| 3. | | |
| 4. | | |
| 5. | | |
| 6. | | |
| 7. | | |
| 8. | | |
| 9. | | |
| 10. | | |
| 11. | | |
| 12. | | |
| 13. | | |
| 14. | | |
| 15. | | |

## SOMEONE YOU THINK HAS THE BEST POSSIBLE LIFE

KEY : 1 = Not a problem
2 = A slight problem
3 = A moderate problem
4 = A big problem
5 = It couldn't be worse

| | | |
|---|---|---|
| 1. | | |
| 2. | | |
| 3. | | |
| 4. | | |
| 5. | | |
| 6. | | |
| 7. | | |
| 8. | | |
| 9. | | |
| 10. | | |
| 11. | | |
| 12. | | |
| 13. | | |
| 14. | | |
| 15. | | |

SOMEONE YOU THINK HAS THE WORST POSSIBLE LIFE

KEY : 1 = Not a problem
2 = A slight problem
3 = A moderate problem
4 = A big problem
5 = It couldn't be worse

| | | |
|---|---|---|
| 1. | | |
| 2. | | |
| 3. | | |
| 4. | | |
| 5. | | |
| 6. | | |
| 7. | | |
| 8. | | |
| 9. | | |
| 10. | | |
| 11. | | |
| 12. | | |
| 13. | | |
| 14. | | |
| 15. | | |

Appendix 6: Copy of Sickness Impact Profile

# HEALTH STATUS QUESTIONNAIRE

# SICKNESS IMPACT PROFILE

PLEASE READ THE WHOLE INTRODUCTION BEFORE
YOU COMPLETE THE QUESTIONNAIRE

## INTRODUCTION

On the next few pages are statements which describe things people often do when they are not well.

As you read them, think of yourself today. When you read a statement that you are sure describes you TODAY AND IS RELATED TO YOUR HEALTH, please put a tick in the box.

FOR EXAMPLE

I am not driving my car.

If you have not been driving for some time because of your health, and are still not driving today, you should tick this statement.

On the other hand, if you never drive or are not driving today because your car is being repaired, the statement, "I am not driving my car" is not related to your health and you should not tick it. If you are driving less, or are driving shorter distances, and feel that the statement only partially describes you, do not tick it. In each of these cases you should leave the box to the right of the statement blank.

Read the introduction to each group of statements and then consider the statements in the order listed. While some of the statements may not apply to you, we ask that you please read all of them. Some of the statements will differ only in a few words, so please read each one carefully. While you may wish to go back to change a response, your first answer is usually the best. Please do not read ahead in the questionnaire.

Once you have started the questionnaire it is very important that you complete it within one day (24 hours).

If you find it hard to keep your mind on the statements, take a short break and then continue from where you left off.

**Please do not discuss the statements with anyone, including family members, while doing the questionnaire.**

Now turn to the questionnaire section and read each statement. Remember we are interested in the recent or longstanding changes in your activities which are related to your health.

## HOW WOULD YOU DESCRIBE YOUR PRESENT HEALTH?

| | | | | |
|---|---|---|---|---|
| Very Good ☐ | Good ☐ | Fair ☐ | Poor ☐ | Very Poor ☐ |

THANK YOU FOR YOUR TIME AND HELP

Patient Number ☐☐☐ Study Number ☐☐☐



PND

PLEASE TICK ONLY THOSE STATEMENTS THAT YOU ARE SURE DESCRIBE YOU TODAY AND ARE RELATED TO YOUR HEALTH

**A** *These statements describe your sleep and rest today*

1 I spend much of the day lying down in order to rest ☐
2 I sit for much of the day ☐
3 I am sleeping or dozing most of the time – day and night ☐
4 I lie down more often during the day in order to rest ☐
5 I sit around half asleep ☐
6 I sleep less at night, for example, I wake up easily, I don't fall asleep for a long time, I keep waking up ☐
7 I sleep or doze more during the day ☐

**B** *The following statements describe your emotional behaviour*

1 I say how bad or useless I am, for example, that I am a burden on others ☐
2 I laugh or cry suddenly ☐
3 I often moan and groan in pain or discomfort ☐
4 I have attempted suicide ☐
5 I behave nervously or restlessly ☐
6 I keep rubbing or holding areas of my body that hurt or are uncomfortable ☐
7 I am irritable and impatient with myself, for example, I run myself down, I swear at myself, I blame myself for things that happen ☐
8 I talk about the future in a hopeless way ☐
9 I get sudden frights ☐

**C** *The following statements describe how you move about, bath, go to the toilet and dress yourself*

1 I make difficult movements with help, for example getting in or out of the bath or a car ☐
2 I do not get in or out of bed or chairs without the help of a person or mechanical aid ☐
3 I only stand for short periods of time ☐
4 I do not keep my balance ☐
5 I move my hands or fingers with some limitation or difficulty ☐
6 I only stand up with someone's help ☐
7 I kneel, stoop or bend down only by holding onto something ☐

PLEASE TICK ONLY THOSE STATEMENTS THAT YOU ARE SURE DESCRIBE YOU TODAY AND ARE RELATED TO YOUR HEALTH

8 I am in a restricted position all the time ☐

9 I am very clumsy ☐

10 I get in and out of bed or chairs by grasping something for support or by using a stick or walking frame ☐

11 I stay lying down most of the time ☐

12 I change position frequently ☐

13 I hold onto something to move myself around in bed ☐

14 I do not bathe myself completely, for example, I need help with bathing ☐

15 I do not bathe myself at all, but am bathed by someone else ☐

16 I use a bedpan with help ☐

17 I have trouble putting on my shoes, socks or stockings ☐

18 I do not have control of my bladder ☐

19 I do not fasten my clothing, for example, I require assistance with buttons, zips or shoelaces ☐

20 I spend most of the time partly dreesed or in pyjamas ☐

21 I do not have control of my bowels ☐

22 I dress myself, but do so very slowly ☐

23 I only get dressed with someone's help ☐

**D** *These statements describe your daily work around the house*

1 I only do housework or work around the house for short periods of time or I rest often ☐

2 I am doing less of the daily household chores that I would usually do ☐

3 I am not doing any of the daily household chores that I would usually do ☐

4 I am not doing any of the maintenance or repair work that I would usually do in my house or garden ☐

5 I am not doing any of the shopping that I would usually do ☐

6 I am not doing any of the cleaning that I would usually do ☐

7 I have difficulty using my hands, for example, turning taps, using kitchen gadgets, sewing or doing repairs ☐

8 I am not doing any of the clothes washing that I would usually do ☐

9 I am not doing heavy work around the house ☐

10 I have given up taking care of personal or household business affairs, for example, paying bills, banking or doing household accounts ☐

PLEASE TICK ONLY THOSE STATEMENTS THAT YOU ARE SURE DESCRIBE YOU TODAY AND ARE RELATED TO YOUR HEALTH

**E** *And these next statements describe how you get about the house and outside*

1 I am only getting about in one building ☐
2 I stay in one room ☐
3 I am staying in bed more ☐
4 I am staying in bed most of the time ☐
5 I am not using public transport now ☐
6 I stay at home most of the time ☐
7 I am only going out if there is a toilet nearby ☐
8 I am not going into town ☐
9 I only stay away from home for short periods ☐
10 I do not get about in the dark or in places that are not lit unless I have someone to help ☐

**F** *These statements describe your contact with your family and friends today*

1 I am going out less to visit people ☐
2 I am not going out to visit people at all ☐
3 I show less interest in other people's problems, for example, I don't listen when they tell me about their problems, I don't offer to help ☐
4 I am often irritable with those around me, for example, I snap at people or criticise easily ☐
5 I show less affection ☐
6 I take part in fewer social activities than I used to, for example, I go to fewer parties or social events ☐
7 I am cutting down the length of visits to friends ☐
8 I avoid having visitors ☐
9 My sexual activity is decreased ☐
10 I often express concern over what might be happening to my health ☐
11 I talk less with those around me ☐

STILL THINKING OF YOURSELF TODAY, PLEASE TICK ONLY THOSE STATEMENTS THAT DESCRIBE YOU, AND YOU ARE SURE ARE RELATED TO YOUR HEALTH

12 I make many demands on other people, for example, I insist that they do things for me, or tell them how to do things ☐

13 I stay alone much of the time ☐

14 I am disagreeable with my family, for example, I act spitefully or stubbornly ☐

15 I frequently get angry with my family, for example, I hit them, scream or throw things at them ☐

16 I isolate myself as much as I can from the rest of my family ☐

17 I am paying less attention to the children ☐

18 I refuse contact with my family, for example, I turn away from them ☐

19 I am not doing the things I usually do to take care of my children or family ☐

20 I am not joking with family members as I usually do ☐

**G** *The next set of statements describe walking and use of stairs*

1 I walk short distances or often stop for a rest ☐

2 I do not walk up or down hills ☐

3 I only use stairs with a physical aid, for example, a handrail, stick or crutches ☐

4 I only go up and down stairs with assistance from someone else ☐

5 I get about in a wheelchair ☐

6 I do not walk at all ☐

7 I walk by myself but with some difficulty, for example, I limp, wobble, stumble or I have a stiff leg ☐

8 I only walk with help from someone else ☐

9 I go up and down stairs more slowly, for example, one step at a time or I often have to stop ☐

10 I do not use stairs at all ☐

11 I get about only by using a walking frame, crutches, stick, walls or hold onto furniture ☐

12 I walk more slowly ☐

AGAIN, PLEASE TICK ONLY THOSE STATEMENTS THAT YOU ARE SURE DESCRIBE YOU TODAY AND ARE RELATED TO YOUR HEALTH

**H** *These statements describe your feelings*

1- I am confused and start to do more than one thing at a time .....

2 I have more minor accidents, for example, I drop things, I trip and fall or bump into things .....

3 I react slowly to things that are said or done .....

4 I do not finish things I start .....

5 I have difficulty reasoning and solving problems, for example, making plans, making decisions, learning new things .....

6 I sometimes get confused, for example, I do not know where I am, who is around, or what day it is .....

7 I forget a lot, for example, things that happened recently, where I put things, or to keep appointments .....

8 I do not keep my attention on any activity for long .....

9 I make more mistakes than usual .....

10 I have difficulty doing things which involve thought and concentration .....

**I** *These statements are about how you talk to other people and write*

1 I am having trouble writing or typing .....

2 I communicate mostly by nodding my head, pointing, or using sign language, or other gestures .....

3 My speech is understood only by a few people who know me well .....

4 I often lose control of my voice when I talk, for example, my voice gets louder or softer or changes unexpectedly .....

5 I don't write except to sign my name .....

6 I carry on a conversation only when very close to other people or looking directly at them .....

7 I speak with difficulty, for example, I get stuck for words, I stutter, I stammer, I slur my words .....

8 I am understood with difficulty .....

9 I do not speak clearly when I am under stress .....

**J** THE NEXT GROUP OF STATEMENTS HAS TO DO WITH ANY WORK YOU USUALLY DO OTHER THAN LOOKING AFTER YOUR HOME – BY THIS WE MEAN ANYTHING THAT YOU REGARD AS WORK THAT YOU DO ON A REGULAR BASIS

Do you usually do work other than looking after your home? ☐ YES ☐ NO

→ If you answered yes, go on to Section **K**

→ If you answered no, complete the following

Are you retired? ☐ YES ☐ NO

If you are retired, was your retirement related to your health? ☐ YES ☐ NO

If you are not retired, but are NOT working, is this related to your health? ☐ YES ☐ NO

Now go on to Section **L** on page 8

**K**

IF YOU ARE NOT WORKING AND IT IS NOT BECAUSE OF YOUR HEALTH, PLEASE GO ON TO THE NEXT PAGE

NOW CONSIDER THE WORK YOU DO AND TICK ONLY THOSE STATEMENTS THAT YOU ARE SURE DESCRIBE YOU TODAY AND ARE RELATED TO YOUR HEALTH. (IF TODAY IS A SATURDAY OR SUNDAY OR SOME OTHER DAY THAT YOU WOULD USUALLY HAVE OFF, PLEASE RESPOND AS IF TODAY WERE A WORKING DAY.)

1 I am not working at all ☐

(IF YOU TICKED THIS STATEMENT, GO ON TO THE NEXT PAGE)

2 I am doing part of my job at home ☐

3 I am not getting as much work done as usual ☐

4 I often get irritable with my workmates, for example, I snap at them and criticise them easily ☐

5 I am working shorter hours ☐

6 I am only doing light work ☐

7 I only work for short periods of time or often stop to rest ☐

8 I work at my usual job but with some changes, for example, I use different tools or special aids, or I swop jobs with someone else ☐

9 I do not do my job as carefully and accurately as usual ☐

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PLEASE TICK ONLY THOSE STATEMENTS THAT YOU ARE SURE DESCRIBE YOU TODAY AND ARE RELATED TO YOUR HEALTH

**L** *The following statements describe the activities you usually do in your spare time, for relaxation, entertainment or just to pass the time*

1 I spend shorter periods of time on my hobbies and recreation ☐
2 I am going out to enjoy myself less often ☐
3 I am cutting down on some of my usual inactive pastimes, for example, I watch less TV, play cards less, or read less ☐
4 I am not doing any of my usual inactive pastimes, for example, I do not watch TV, play cards or read ☐
5 I am doing more inactive pastimes in place of my other usual activities ☐
6 I am taking part in fewer community activities ☐
7 I am cutting down on some of my usual physical recreation or more active pastimes ☐
8 I am not doing any of my usual physical recreation or more active pastimes ☐

**M** *The following statements describe your eating and drinking habits*

1 I am eating much less than usual ☐
2 I feed myself but only with specially prepared food or special utensils ☐
3 I am eating special or different food, for example, soft food, bland diet, low-salt, low-fat, low-sugar ☐
4 I eat no food at all but I take liquids ☐
5 I just pick or nibble at my food ☐
6 I am drinking less fluids ☐
7 I feed myself with help from someone else ☐
8 I do not feed myself at all but have to be fed ☐
9 I am eating no food at all except by tubes or intravenous infusion ☐

NOW PLEASE LOOK THROUGH THIS QUESTIONNAIRE AND MAKE SURE THAT YOU HAVE READ EVERY QUESTION.

THANK YOU ONCE AGAIN FOR YOUR HELP.

What date is it today? ..... 19 .....

Appendix 7: Copy of Mood Adjective Checklist

## MOOD ADJECTIVE CHECK LIST

Name ..... Ward ..... Date .....

Below are a number of words which describe moods. Please put a cross to indicate how much you have felt the way described in the last 24 hours.

| | Not at all | A little | Quite a bit | Extremely |
|---|---|---|---|---|
| Shaky | | | | |
| Sluggish | | | | |
| Resentful | | | | |
| Nervous | | | | |
| Weary | | | | |
| Vigorous | | | | |
| Hopeless | | | | |
| Lively | | | | |
| Guilty | | | | |
| Tired | | | | |
| Unhappy | | | | |
| Tense | | | | |
| Full of pep | | | | |
| Active | | | | |
| Worthless | | | | |
| Miserable | | | | |
| Worn out | | | | |
| Discouraged | | | | |
| Spiteful | | | | |
| Depressed | | | | |
| On edge | | | | |
| Angry | | | | |
| Furious | | | | |
| Helpless | | | | |

Appendix 8: Copy of Life Events Schedule

LIFE EVENTS SCALE (adapted from Sarason et al 1978)

Listed below are a number of events which sometimes bring about a change in the lives of people who experience them. Please indicate if any of these events have happened to you in the last few weeks/months, by placing a tick next to the event.

Also, please rate how you think the event affected your life, whether it had a positive(good) effect or a negative(bad) effect, by circling the appropriate number.

Rating scale : -2 = very negative effect
-1 = slightly negative effect
0 = no noticeable effect
1 = slightly positive effect
2 = very positive effect

---

| | | | | | |
|---|---|---|---|---|---|
| 1. Marriage | -2 | -1 | 0 | 1 | 2 |
| 2. Death of spouse | -2 | -1 | 0 | 1 | 2 |
| 3. Major change in sleeping habits (much more or much less sleep) | -2 | -1 | 0 | 1 | 2 |
| 4. Death of close family member | | | | | |
| a. Mother | -2 | -1 | 0 | 1 | 2 |
| b. Father | -2 | -1 | 0 | 1 | 2 |
| c. Sister | -2 | -1 | 0 | 1 | 2 |
| d. Brother | -2 | -1 | 0 | 1 | 2 |
| e. Grandmother | -2 | -1 | 0 | 1 | 2 |
| f. Grandfather | -2 | -1 | 0 | 1 | 2 |
| g. Other (specify) | -2 | -1 | 0 | 1 | 2 |
| 5. Major change in eating habits (eating much more or much less) | -2 | -1 | 0 | 1 | 2 |
| 6. Death of close friend | -2 | -1 | 0 | 1 | 2 |
| 7. Outstanding personal achievement | -2 | -1 | 0 | 1 | 2 |
| 8. Minor law violations | -2 | -1 | 0 | 1 | 2 |
| 9. Pregnancy - own/partners | -2 | -1 | 0 | 1 | 2 |
| 10. Change in work situation (different responsibility, conditions, hours) | -2 | -1 | 0 | 1 | 2 |
| 11. New job | -2 | -1 | 0 | 1 | 2 |
| 12. Serious illness/injury of close family member | | | | | |
| a. Mother | -2 | -1 | 0 | 1 | 2 |
| b. Father | -2 | -1 | 0 | 1 | 2 |
| c. Sister | -2 | -1 | 0 | 1 | 2 |
| d. Brother | -2 | -1 | 0 | 1 | 2 |
| e. Grandmother | -2 | -1 | 0 | 1 | 2 |
| f. Grandfather | -2 | -1 | 0 | 1 | 2 |
| g. Other (specify) | -2 | -1 | 0 | 1 | 2 |
| 13. Sexual difficulties | -2 | -1 | 0 | 1 | 2 |
| 14. Trouble with employer (fear of losing job) | -2 | -1 | 0 | 1 | 2 |
| 15. Major change in financial status (much better or worse off) | -2 | -1 | 0 | 1 | 2 |
| 16. Gaining new family member (birth, adoption) | -2 | -1 | 0 | 1 | 2 |
| 17. Marital problems (rows,separation, divorce) | -2 | -1 | 0 | 1 | 2 |
| 18. Major change in church activities (increased, decreased attendance) | -2 | -1 | 0 | 1 | 2 |
| 19. Major change in usual type/amount of recreation | -2 | -1 | 0 | 1 | 2 |
| 20. Being fired from job | -2 | -1 | 0 | 1 | 2 |

| | | | | | |
|---|---|---|---|---|---|
| 21. Major personal illness/injury | -2 | -1 | 0 | 1 | 2 |
| 22. Major change in social activities (increased/decreased participation) | -2 | -1 | 0 | 1 | 2 |
| 23. Major change in living conditions of family (building new home,deterioration of home etc) | -2 | -1 | 0 | 1 | 2 |
| 24. Serious illness or injury of close friend | -2 | -1 | 0 | 1 | 2 |
| 25. Retirement from work | -2 | -1 | 0 | 1 | 2 |
| 26. Engagement | -2 | -1 | 0 | 1 | 2 |
| 27. Breaking up with girlfriend/boyfriend | -2 | -1 | 0 | 1 | 2 |
| 28. Leaving home for the first time | -2 | -1 | 0 | 1 | 2 |
| 29. Reconciliation with girlfriend/boyfriend | -2 | -1 | 0 | 1 | 2 |
| 30. Change of residence | -2 | -1 | 0 | 1 | 2 |
| 31. Any other events which have had an impact on your life. Please list and rate : | | | | | |
| _____ | -2 | -1 | 0 | 1 | 2 |
| _____ | -2 | -1 | 0 | 1 | 2 |
| _____ | -2 | -1 | 0 | 1 | 2 |

Thank you for your time.

Appendix 9: Copy of Global Rating Scale

## QUALITY OF LIFE STUDY - GLOBAL RATING SCALES

Patient name _____ Number_____

Date _____ Session No. _____ Investigator _____

INSTRUCTIONS

The following questions are aimed at obtaining a general view of how satisfied you are with certain areas of your life today.

Please tick the box which best describes how satisfied you are with each area today.

1. How satisfied are you with your life in general today?

| | | | | |
|---|---|---|---|---|
| very satisfied | slightly satisfied | neither satisfied nor dissatisfied | slightly dissatisfied | very dissatisfied |

2. How satisfied are you with your PHYSICAL HEALTH today ? ( ie. how happy are you with your fits, your ability to perform physical activities, to see, to hear, to move around etc.)

| | | | | |
|---|---|---|---|---|
| very satisfied | slightly satisfied | neither satisfied nor dissatisfied | slightly dissatisfied | very dissatisfied |

3. How satisfied are you with your COGNITIVE ABILITY (ie. how happy are you with your memory, concentration, decision making ability etc.) today ?

| | | | | |
|---|---|---|---|---|
| very satisfied | slightly satisfied | neither satisfied nor dissatisfied | slightly dissatisfied | very dissatisfied |

4. How satisfied are you with your EMOTIONAL STATUS today ? (ie. how happy are you with your ability to be happy, to cope with stress, to keep your temper, to be in control of your life etc.)

| | | | | |
|---|---|---|---|---|
| very satisfied | slightly satisfied | neither satisfied nor dissatisfied | slightly dissatisfied | very dissatisfied |

5. How satisfied are you with your SOCIAL FUNCTIONING today ? (ie. how happy are you with your relationships with your family, your ability to make friends, to get on with others, how you spend your spare time, your social life etc.)

| | | | | |
|---|---|---|---|---|
| very satisfied | slightly satisfied | neither satisfied nor dissatisfied | slightly dissatisfied | very dissatisfied |

6. How satisfied are you with your EMPLOYMENT today ? (ie. how happy are you with your job or daytime activity? Do you feel you are doing something worthwhile, are you using your skills/abilities etc.)

| | | | | |
|---|---|---|---|---|
| very satisfied | slightly satisfied | neither satisfied nor dissatisfied | slightly dissatisfied | very dissatisfied |

7. How satisfied are you with your FINANCES today ? (ie. how happy are you with the money you receive? Do you have enough money to provide a reasonable standard of living, do you have sufficient funds for all your needs, do you have any financial debts etc.)

| | | | | |
|---|---|---|---|---|
| very satisfied | slightly satisfied | neither satisfied nor dissatisfied | slightly dissatisfied | very dissatisfied |

Appendix 10: Copy of Construct Importance Scale

## CONSTRUCT IMPORTANCE SCALE

Please rate how important the following areas are for you to be happy and satisfied with your life.

KEY : 1 = Of no importance
2 = Slightly important
3 = Moderately important
4 = Very important
5 = Extremely important

| | | |
|---|---|---|
| 1. | | |
| 2. | | |
| 3. | | |
| 4. | | |
| 5. | | |
| 6. | | |
| 7. | | |
| 8. | | |
| 9. | | |
| 10. | | |
| 11. | | |
| 12. | | |
| 13. | | |
| 14. | | |
| 15. | | |

Appendix 11: Copy of McGill Questionnaire

# MCGILL PAIN QUESTIONNAIRE

A. Choose one word group to describe your pain

1. Continous, Steady, Constant [ ]
2. Rhythmic, Periodic, Intermittent [ ]
3. Brief, Momentary, Transient [ ]

B. The following words describe pain of increasing severity

1=nil 2=mild 3=moderate 4=severe 5=most severe

Choose the number of the word which best describes:

1) Your pain right now [ ]
2) Your pain at its worse [ ]
3) Your pain at its least [ ]

C. What does your pain feel like?

Some of the words listed below will describe your present pain. Circle the words which best describe it. Leave out any word group that is not suitable. Use only a single word in each appropriate group -- the one that applied best.

| 1 | 2 | 3 | 4 |
|---|---|---|---|
| 1 Flickering | 1 Jumping | 1 Pricking | 1 Sharp |
| 2 Quivering | 2 Flashing | 2 Boring | 2 Cutting |
| 3 Pulsing | 3 Shooting | 3 Drilling | 3 Lacerating |
| 4 Throbbing | | 4 Stabbing | |
| 5 Beating | | 5 Lancinating | |
| 6 Pounding | | | |

| 5 | 6 | 7 | 8 |
|---|---|---|---|
| 1 Pinching | 1 Tugging | 1 Hot | 1 Tingling |
| 2 Pressing | 2 Pulling | 2 Burning | 2 Itchy |
| 3 Gnawing | 3 Wrenching | 3 Scalding | 3 Smarting |
| 4 Cramping | | 4 Searing | 4 Stinging |
| 5 Crushing | | | |

| 9 | 10 | 11 | 12 |
|---|---|---|---|
| 1 Dull | 1 Tender | 1 Tiring | 1 Sickening |
| 2 Sore | 2 Taut | 2 Exhausting | 2 Suffocating |
| 3 Hurting | 3 Rasping | | |
| 4 Aching | 4 Splitting | | |
| 5 Heavy | | | |

| 13 | 14 | 15 | 16 |
|---|---|---|---|
| 1 Fearful | 1 Punishing | 1 Wretched | 1 Annoying |
| 2 Frightful | 2 Gruelling | 2 Blinding | 2 Troublesome |
| 3 Terrifying | 3 Cruel | | 3 Miserable |
| | 4 Vicious | | 4 Intense |
| | 5 Killing | | 5 Unbearable |

| 17 | 18 | 19 | 20 |
|---|---|---|---|
| 1 Spreading | 1 Tight | 1 Cool | 1 Nagging |
| 2 Radiating | 2 Numb | 2 Cold | 2 Nauseating |
| 3 Penetrating | 3 Drawing | 3 Freezing | 3 Agonizing |
| 4 Piercing | 4 Squeezing | | 4 Dreadful |
| | 5 Tearing | | 5 Torturing |

Appendix 12: Copy of HAD scale

# HAD Scale

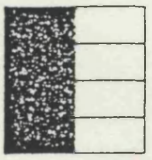
Name: Date:

Doctors are aware that emotions play an important part in most illnesses. If your doctor knows about these feelings he will be able to help you more.
This questionnaire is designed to help your doctor to know how you feel. Read each item and place a firm tick in the box opposite the reply which comes closest to how you have been feeling in the past week.
Don't take too long over your replies: your immediate reaction to each item will probably be more accurate than a long thought-out response.

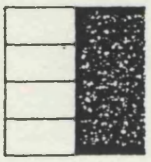
*Tick only one box in each section*

**I feel tense or 'wound up':**
- Most of the time .....
- A lot of the time .....
- Time to time, Occasionally .....
- Not at all .....

**I still enjoy the things I used to enjoy:**
- Definitely as much .....
- Not quite so much .....
- Only a little .....
- Hardly at all .....



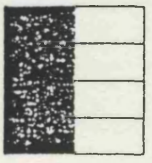
**I get a sort of frightened feeling as if something awful is about to happen:**
- Very definitely and quite badly .....
- Yes, but not too badly .....
- A little, but it doesn't worry me .....
- Not at all .....



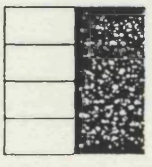
**I can laugh and see the funny side of things:**
- As much as I always could .....
- Not quite so much now .....
- Definitely not so much now .....
- Not at all .....

**Worrying thoughts go through my mind:**
- A great deal of the time .....
- A lot of the time .....
- From time to time but not too often ...
- Only occasionally .....

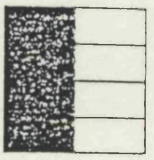
**I feel cheerful:**
- Not at all .....
- Not often .....
- Sometimes .....
- Most of the time .....



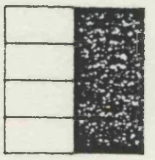
**I can sit at ease and feel relaxed:**
- Definitely .....
- Usually .....
- Not often .....
- Not at all .....



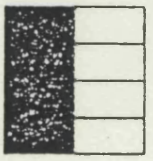
**I feel as if I am slowed down:**
- Nearly all the time .....
- Very often .....
- Sometimes .....
- Not at all .....



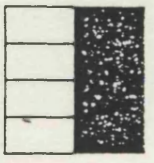
**I get a sort of frightened feeling like 'butterflies' in the stomach:**
- Not at all .....
- Occasionally .....
- Quite often .....
- Very often .....



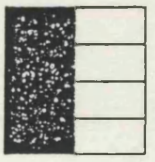
**I have lost interest in my appearance:**
- Definitely .....
- I don't take so much care as I should.....
- I may not take quite as much care .....
- I take just as much care as ever .....



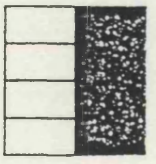
**I feel restless as if I have to be on the move:**
- Very much indeed .....
- Quite a lot .....
- Not very much .....
- Not at all .....



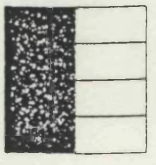
**I look forward with enjoyment to things:**
- As much as ever I did .....
- Rather less than I used to .....
- Definitely less than I used to .....
- Hardly at all .....



**I get sudden feelings of panic:**
- Very often indeed .....
- Quite often .....
- Not very often .....
- Not at all .....



**I can enjoy a good book or radio or TV programme:**
- Often .....
- Sometimes .....
- Not often .....
- Very seldom .....



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Appendix 13: Interview schedule used with trigeminal neuralgia group

VERSION 2
(TRIGEMINAL
NEURALGIA GROUP)

## REPERTORY GRID INTERVIEW

Name/Study number: _____

Address: _____

_____

_____

Telephone number: _____

Date of birth: _____ Hospital number: _____

Ravens Matrices/NART: _____

## ADDITIONAL INFORMATION

## CONSTRUCT ELICITATION

| | | |
|---|---|---|
| 1 5 6 | _____ | Physical |
| 1 9 10 | _____ | 1. |
| 1 2 3 | _____ | 2. |
| 1 3 9 | _____ | Cognitive |
| 1 6 7 | _____ | 1. |
| 1 4 5 | _____ | 2. |
| 1 2 10 | _____ | Emotional |
| 1 8 9 | _____ | 1. |
| 3 9 10 | _____ | 2. |
| 1 3 4 | _____ | Social |
| 2 3 4 | _____ | 1. |
| 8 9 10 | _____ | 2. |
| 1 7 8 | _____ | Econ/Work |
| 6 7 8 | _____ | 1. |
| 4 5 6 | _____ | 2. |
| 7 8 9 | _____ | Free |
| 3 4 5 | _____ | 1. |
| | _____ | 2. |
| | _____ | 3. |
| | _____ | 4. |
| | _____ | 5. |
| | _____ | |

_____

_____

_____

_____

_____

_____

Appendix 14: Demographic details of epilepsy patients (Studies 1 and 2 all patients with data on at least 2 occasions.

| | All patients N=50 | Study 1 N=24 | Study 2 N=26 |
|---|---|---|---|
| Age | | | |
| Mean (SD) | 44.6 (12.2) | 45 (11.8) | 44.3 (12.8) |
| Median (Range) | 44 (20-72) | 44 (26-66) | 44 (20-72) |
| Sex | | | |
| Male:Female | 41:9 | 19:5 | 22:4 |
| Handedness | | | |
| Right:Left | 41:9 | 22:2 | 19:7 |
| Marital status | | | |
| Single | 47 | 22 | 25 |
| Married | 2 | 1 | 1 |
| Divorced | 1 | 1 | 0 |
| Education | | | |
| Special school | 13 | 5 | 8 |
| Main stream | 37 | 19 | 18 |
| Qualifications | | | |
| None | 37 | 19 | 18 |
| CSE's | 3 | 1 | 2 |
| 'O' levels | 4 | 2 | 2 |
| Vocational | 6 | 2 | 4 |
| Accomodation | | | |
| Main centre | 40 | 14 | 26 |
| Hostel | 10 | 10 | 0 |
| Occupation | | | |
| Unemployed | 3 | 1 | 2 |
| Open (P/T) | 1 | 1 | 0 |
| Open (F/T) | 0 | 0 | 0 |
| Voluntary | 2 | 2 | 0 |
| Sheltered | 39 | 16 | 23 |
| Retired | 5 | 4 | 1 |
| Ever in open employment? | | | |
| Yes:No | 25:25 | 16:8 | 9:17 |
| Years in open employment | | | |
| Mean (SD) | 9.2 (10.2) | 7.7 (9.1) | 11.6 (12.0) |
| Median (Range) | 4.5 (1-35) | 4.0 (1-35) | 8 (1-30) |
| Neurological deficit | | | |
| Yes:No | 10:40 | 1:23 | 9:17 |
| Psychiatric history | | | |
| Yes:No | 12:38 | 8:16 | 4:22 |
| Psychological deficit | | | |
| Yes:No | 8:42 | 1:23 | 7:19 |
| Intellectual level | | | |
| FSIQ: Mean (SD) | 88.2 (10.2) | 90 (10.1) | 86.5 (10.3) |
| PIQ : Mean (SD) | 85.4 (11.7) | 86.1 (11.6) | 83.8 (11.8) |
| VIQ : Mean (SD) | 89.0 (10.3) | 89.1 (9.8) | 88.9 (11.0) |

Appendix 15: Epilepsy details:all epilepsy patients with data on at least 2 occasions.

| | All patients N=50 | Study 1 N=24 | Study 2 N=26 |
|---|---|---|---|
| Age of onset (yrs) | | | |
| Mean (SD) | 8.8 (6.1) | 10.1 (5.4) | 7.5 (6.6) |
| Median (Range | 8.5 (1-32) | 10.0 (1-20) | 6.5 (1-32) |
| Duration (yrs) | | | |
| Mean (SD) | 35.2 (11.0) | 34.9 (10.4) | 35.5 (11.9) |
| Median (Range) | 33.5 (12-59) | 35.0 (12-54) | 32.0 (13-59 |
| Aetiology | | | |
| Known:Unknown | 20:30 | 8:16 | 12:14 |
| Family history | | | |
| Yes:No | 9:41 | 4:20 | 5:21 |
| History of status | | | |
| Yes:No | 17:33 | 6:18 | 11:15 |
| EEG | | | |
| Normal | 2 | 1 | 1 |
| Left sided | 13 | 7 | 6 |
| Right sided | 9 | 3 | 6 |
| Bilateral | 6 | 2 | 4 |
| Generalised | 20 | 11 | 9 |
| Seizure type (no of patients) | | | |
| IA | 2 | 0 | 2 |
| IB | 36 | 16 | 20 |
| IC | 37 | 18 | 19 |
| PG: | 7 | 5 | 2 |
| IIA | 0 | 0 | 0 |
| IIB | 1 | 1 | 0 |
| IID | 1 | 0 | 1 |
| IIE | 7 | 5 | 2 |
| IIF | 2 | 1 | 1 |
| Number of seizure types | | | |
| 1 | 13 | 6 | 7 |
| 2 | 35 | 18 | 17 |
| 3 | 2 | 0 | 2 |

Appendix 16: Medication details: all patients with data on at least 2 occasions.

| | All patients N=50 | Study 1 N=24 | Study 2 N=26 |
|---|---|---|---|
| PHENYTOIN | | | |
| N | 23 | 14 | 9 |
| Mean (SD) | 362 (75.3) | 370 (67.4) | 350 (89.3) |
| Med (Range) | 350 (200-500) | 363 (275-500) | 350 (200-500) |
| CARBAMAZEPINE | | | |
| N | 31 | 13 | 18 |
| Mean (SD) | 1256 (360.5) | 1185 (378.3) | 1256 (355.2) |
| Med (Range) | 1200 (600-1800) | 1200 (600-1800) | 1200 (800-1800) |
| SODIUM VALPROATE | | | |
| N | 15 | 8 | 7 |
| Mean (SD | 1840 (631) | 2000 (598) | 1657 (663) |
| Med (Range) | 2000 (600-3000) | 2000 (1000-3000) | 2000 (600-2500) |
| PHENOBARBITONE | | | |
| N | 2 | 1 case only: | 1 case only: |
| Mean (SD) | 135 (21.2) | 150 mg daily | 120 mg daily |
| Med (Range) | 135 (120-150) | | |
| PRIMIDONE | | | |
| N | 16 | 7 | 9 |
| Mean (SD) | 675 (291.5) | 821 (278.2) | 561 (260.7) |
| Med (Range) | 750 (50-1250) | 750 (500-1250) | 750 (50-750) |
| ETHOSUXIMIDE | | | |
| N | 1 case only: | 1 case only: | No cases |
| Mean (SD) | 500 mg daily | 500 mg daily | |
| Med (Range) | | 10.0 (1-20) | |
| CLOBAZAM | | | |
| N | 12 | 3 cases: all | 9 |
| Mean (SD) | 12.9 (6.9) | 10 mg daily | 12.8 (7.5) |
| Med (Range) | 10.0 (5-30) | | 10 (5-30) |
| CO-MED (non-AED) | | | |
| Yes:No | 29:21 | 15:9 | 14:12 |

N,number of patients; CO-MED, co-medication; AED, antiepileptic drug; Med, median; SD, standard deviation.

Appendix 17: Frequency measures (mean, SD, median, range) for RG-based measures of QOL (aggregate and profile)

| Variable | Statistic | Session 1 | 2 | 3 | 4 |
|---|---|---|---|---|---|
| **Aggregate Measures:** | | | | | |
| ABS | Mean (SD) | 12 (8) | 10 (7) | 10 (7) | 10 (8) |
| | Med (Range) | 11 (0-32) | 10 (0-34) | 9 (0-31) | 10 (0-36) |
| DIR | Mean (SD) | 11 (8) | 10 (8) | 10 (7) | 9 (8) |
| | Med (Range) | 9 (-4-32) | 9 (0-34) | 9 (-1-31) | 8 (0-36) |
| ABS6 | Mean (SD) | 4.3 (1.3) | 4.2 (1.4) | 4.1 (1.2) | 4.1 (1.4) |
| | Med (Range) | 5 (1-6) | 4.5 (1-6) | 4.5 (1-6) | 4.5 (1-6) |
| DIR6 | Mean (SD) | 4.6 (1.1) | 4.2 (1.4) | 4.3 (1.1) | 4.5 (1.0) |
| | Med (Range) | 5 (1-6) | 4 (1-6) | 4.5 (1-6) | 4.3 (2-6) |
| ABS21 | Mean (SD) | 12.2 (5.3) | 12 (5.7) | 12 (5.3) | 11.4(6.1) |
| | Med (Range) | 12.3 (1-21) | 12 (2-21) | 12 (1-21) | 11.3(1-21) |
| **Profile (Method 1) Measures:** | | | | | |
| PHYS1 | Mean (SD) | 16.2 (11.5) | 16.4 (13.5) | 16.8 (13.7) | 17.6 (13.3) |
| | Med (Range) | 17 (0-40) | 14 (0-48) | 13 (0-52) | 15 (0-48) |
| COG1 | Mean (SD) | 18.2 (14.6) | 14.3 (12.8) | 15.1 (13.8) | 13.8 (14.1) |
| | Med (Range) | 13 (0-52) | 12 (0-50) | 12 (0-50) | 10 (0-50) |
| EMOT1 | Mean (SD) | 23.8 (20.5) | 20.5 (20.1) | 19.3 (17.5) | 19.9 (19.7) |
| | Med (Range) | 20 (0-81) | 15 (0-87) | 16 (0-89) | 15 (0-86) |
| SOC1 | Mean (SD) | 22.2 (19.1) | 19.0 (15.5) | 16.4 (13.7) | 15.3 (13.3) |
| | Med (Range) | 18 (0-75) | 18 (0-58) | 17 (0-62) | 14.5 (0-52) |
| WORK1 | Mean (SD) | 15.7 (15.9) | 14.3 (14.9) | 15.1 (12.3) | 12.1 (12.8) |
| | Med (Range) | 12 (0-67) | 9 (0-55) | 11 (9-49) | 8.5 (0-51) |
| **Profile (Method 2) Measures:** | | | | | |
| PHYS2 | Mean (SD) | 2.2 (1.7) | 2.1 (1.9) | 2.1 (1.9) | 2.3 (2.1) |
| | Med (Range) | 2 (0-6) | 2 (0-6) | 2 (0-7) | 2 (0-8) |
| COG2 | Mean (SD) | 2.8 (2.3) | 2.2 (2) | 2.2 (2.2) | 2.1 (2.2) |
| | Med (Range) | 2 (0-7) | 2 (0-7) | 2 (0-8) | 1 (0-8) |
| EMOT2 | Mean (SD) | 2.1 (2.1) | 1.7 (2.1) | 1.7 (1.9) | 1.9 (2.1) |
| | Med (Range) | 2 (0-8) | 1 (0-8) | 1 (0-8) | 1 (0-8) |
| SOC2 | Mean (SD) | 2.5 (2.1) | 2.1 (1.8) | 1.5 (1.5) | 1.7 (1.7) |
| | Med (Range) | 2 (0-8) | 2 (0-7) | 1 (0-5) | 1 (0-6) |
| WORK2 | Mean (SD) | 2.2 (2.2) | 2.1 (2.3) | 2.3 (2) | 1.7 (2.1) |
| | Med (Range) | 2 (0-8) | 2 (0-8) | 2 (0-7) | 1 (0-8) |

Group numbers: S1=50, S2=49, S3=47, S4=44.

Med, median; SD, standard deviation; PHYS, physical abilities; COG, cognitive status; EMOT, emotional status; SOC, social functioning; WORK, economic/employment situation.

Note: Maximum possible scores - ABS/DIR = 40
ABS6/DIR6 = 6
ABS21 = 21
PHYS1 - WORK1 = 240
PHYS2 - WORK2 = 8

Appendix 18: Aggregate RG measures: summary of 1-way anova by gender (session 1 data, epilepsy patients only).

| Variable | ALL EPILEPSY PATIENTS (41 male:9 female) | | MATCHED GROUP (9 male: 9 female) | |
|---|---|---|---|---|
| | F | p | F | p |
| ABS | 0.02 | 0.88 | 0.001 | 0.98 |
| DIR | 0.001 | 0.97 | 0.04 | 0.83 |
| ABS6 | 1.50 | 0.23 | 1.03 | 0.33 |
| DIR6 | 1.40 | 0.24 | 1.72 | 0.21 |
| ABS21 | 2.37 | 0.13 | 1.55 | 0.23 |

Appendix 19: Correlation of negative life events with change in aggregate RG measures (N=24).

| Variable | | Session Pairing | | | | | |
|---|---|---|---|---|---|---|---|
| | | 1v2 | 2v3 | 3v4 | 1v4 | 2v4 | 1v3 |
| ABS | r | -.18 | -.40 | .37 | .05 | .28 | -.01 |
| | p | .41 | .05 | .08 | .81 | .19 | .95 |
| DIR | r | -.11 | -.18 | .44 | .10 | .38 | .27 |
| | p | .62 | .41 | .03 | .65 | .06 | .20 |
| ABS6 | r | .06 | -.34 | -.09 | -.07 | .32 | .33 |
| | p | .77 | .11 | .69 | .74 | .12 | .12 |
| DIR6 | r | .13 | -.12 | .14 | .13 | .35 | .06 |
| | p | .53 | .57 | .52 | .55 | .10 | .79 |
| ABS21 | r | -.02 | -.36 | .23 | -.09 | .29 | .40 |
| | p | .94 | .08 | .27 | .68 | .17 | .05 |

Spearmans correlations.
Only patients with valid RG and LES data on all 4 occasions (n=24) were included in the analysis.

Appendix 20: Correlation of positive life events with change in aggregate RG measures (N=24).

| Variable | | Session Pairing | | | | | |
|---|---|---|---|---|---|---|---|
| | | 1v2 | 2v3 | 3v4 | 1v4 | 2v4 | 1v3 |
| ABS | r | -.20 | -.08 | -.09 | .09 | -.01 | -.17 |
| | p | .37 | .71 | .69 | .67 | .98 | .44 |
| DIR | r | .03 | .04 | -.29 | -.20 | .06 | -.11 |
| | p | .91 | .85 | .17 | .36 | .78 | .62 |
| ABS6 | r | .15 | .20 | .04 | -.02 | .11 | .08 |
| | p | .49 | .36 | .85 | .91 | .60 | .72 |
| DIR6 | r | -.07 | .33 | .004 | -.36 | .08 | -.02 |
| | p | .74 | .12 | .98 | .09 | .71 | .94 |
| ABS21 | r | -.05 | .14 | -.03 | -.02 | .005 | -.10 |
| | p | .83 | .53 | .87 | .93 | .98 | .65 |

Spearman correlations, absolute change scores ie. abs (dir1-dir4).
Cases with valid data on all 4 occasions only (n=24).

Appendix 21: Correlation of total life events with change in aggregate RG measures (N=24).

| | | Session Pairing | | | | | |
|---|---|---|---|---|---|---|---|
| Variable | | 1v2 | 2v3 | 3v4 | 1v4 | 2v4 | 1v3 |
| ABS | r | -.33 | -.21 | .20 | .03 | .16 | -.20 |
| | p | .12 | .33 | .35 | .87 | .45 | .34 |
| DIR | r | .02 | -.06 | .08 | -.02 | .27 | -.04 |
| | p | .94 | .78 | .71 | .94 | .20 | .85 |
| ABS6 | r | .18 | .05 | .03 | .15 | .19 | .22 |
| | p | .41 | .83 | .91 | .49 | .39 | .31 |
| DIR6 | r | -.03 | .19 | .17 | -.06 | .24 | .10 |
| | p | .90 | .36 | .43 | .78 | .26 | .64 |
| ABS21 | r | -.04 | -.003 | .11 | .12 | .13 | .15 |
| | p | .86 | .99 | .61 | .57 | .54 | .49 |

Spearman correlations
Cases with valid LES and RG data on all 4 occasions only (n=24).

Appendix 22: Correlation of discrepancy in negative and positive life events with change in aggregate RG measures (N=24).

| | | Session Pairing | | | | | |
|---|---|---|---|---|---|---|---|
| Variable | | 1v2 | 2v3 | 3v4 | 1v4 | 2v4 | 1v3 |
| ABS | r | .06 | .13 | -.21 | .10 | -.08 | -.02 |
| | p | .78 | .55 | .32 | .65 | .70 | .92 |
| DIR | r | .08 | .13 | -.40 | -.15 | -.22 | -.18 |
| | p | .72 | .55 | .05 | .49 | .31 | .40 |
| ABS6 | r | .06 | .38 | .13 | .10 | -.01 | -.16 |
| | p | .78 | .06 | .55 | .64 | .95 | .47 |
| DIR6 | r | -.26 | .34 | -.04 | -.46 | -.22 | -.21 |
| | p | .23 | .11 | .87 | .02 | .30 | .33 |
| ABS21 | r | -.08 | .32 | -.13 | .14 | -.09 | -.40 |
| | p | .71 | .13 | .56 | .51 | .67 | .05 |

LES discrepancy calculated as (LES positive score-LES negative score. Takes direction of change into account. A negative discrepancy score indicates that more negative than positive events have occurred while a positive discrepancy score indicates that more positive events have occurred.

Appendix 23: Profile RG measures: summary of 1-way anova by gender (session 1 data, epilepsy patients only).

| Variable | ALL EPILEPSY PATIENTS (41 male:9 female) F | p | MATCHED GROUP (9 male: 9 female) F | p |
|---|---|---|---|---|
| Method 1 | | | | |
| PHYS1 | 0.03 | 0.86 | 0.008 | 0.93 |
| COG1 | 0.24 | 0.63 | 0.06 | 0.80 |
| EMOT1 | 0.36 | 0.55 | 0.0008 | 0.98 |
| SOC1 | 0.0001 | 0.99 | 0.08 | 0.78 |
| WORK1 | 0.07 | 0.79 | 0.73 | 0.40 |
| Method 2 | | | | |
| PHYS2 | -0.81 | 0.42 | -0.14 | 0.89 |
| COG2 | -0.21 | 0.83 | -0.29 | 0.77 |
| EMOT2 | -0.57 | 0.57 | -0.13 | 0.89 |
| SOC2 | -0.35 | 0.73 | -0.05 | 0.96 |
| WORK2 | -0.23 | 0.82 | -0.82 | 0.41 |

PHYS, physical abilities; COG, cognitive status; EMOT, emotional status; SOC, social functioning; WORK, economic/employment situation.

Appendix 24: Correlation of negative life events with change in profile RG measures (method 1) (N=24).

| Variable | | Session Pairing 1v2 | 2v3 | 3v4 | 1v4 | 2v4 | 1v3 |
|---|---|---|---|---|---|---|---|
| PHYS1 | r | -.03 | -.01 | .43 | -.14 | .30 | -.01 |
| | p | .88 | .95 | .04 | .52 | .16 | .96 |
| COG1 | r | -.21 | .14 | .31 | .31 | .56 | .09 |
| | p | .33 | .53 | .14 | .14 | .004 | .67 |
| EMOT1 | r | .25 | .02 | .38 | .34 | .41 | .24 |
| | p | .24 | .93 | .06 | .11 | .05 | .26 |
| SOC1 | r | -.10 | -.03 | .25 | .10 | .13 | .09 |
| | p | .65 | .89 | .24 | .64 | .54 | .67 |
| WORK1 | r | -.18 | -.07 | -.02 | .16 | .12 | -.09 |
| | p | .41 | .74 | .93 | .47 | .59 | .68 |

Spearmans correlations.
Only patients with valid RG and LES data on all 4 occasions (n=24) were included in the analysis.

Appendix 25: Correlation of positive life events with change in profile RG measures (method 1) (N=24).

| | Session Pairing | | | | | |
|---|---|---|---|---|---|---|
| Variable | 1v2 | 2v3 | 3v4 | 1v4 | 2v4 | 1v3 |
| PHYS1 r | -.22 | .05 | -.12 | -.36 | .04 | -.27 |
| p | .30 | .82 | .57 | .09 | .87 | .20 |
| COG1 r | -.31 | -.38 | .05 | -.09 | -.25 | -.14 |
| p | .15 | .07 | .80 | .69 | .23 | .52 |
| EMOT1 r | -.17 | -.08 | -.03 | .01 | .31 | .13 |
| p | .42 | .73 | .88 | .98 | .15 | .54 |
| SOC1 r | .05 | -.13 | -.18 | -.01 | -.16 | .20 |
| p | .81 | .55 | .39 | .97 | .46 | .35 |
| WORK1 r | .22 | .03 | -.08 | .08 | -.05 | .13 |
| p | .31 | .89 | .70 | .70 | .83 | .54 |

Spearmans correlations.
Only patients with valid RG and LES data on all 4 occasions (n=24) were included in the analysis.

Appendix 26: Correlation of total life events with change in profile RG measures (method 1) (N=24).

| | Session Pairing | | | | | |
|---|---|---|---|---|---|---|
| Variable | 1v2 | 2v3 | 3v4 | 1v4 | 2v4 | 1v3 |
| PHYS1 r | -.23 | -.02 | .20 | -.11 | .25 | -.20 |
| p | .28 | .94 | .36 | .60 | .24 | .36 |
| COG1 r | -.36 | -.27 | .26 | .17 | .01 | -.13 |
| p | .09 | .21 | .23 | .44 | .97 | .55 |
| EMOT1 r | -.07 | -.10 | .20 | .14 | .49 | .10 |
| p | .76 | .65 | .35 | .51 | .01 | .66 |
| SOC1 r | -.03 | -.02 | .02 | .10 | -.05 | .17 |
| p | .87 | .91 | .93 | .63 | .80 | .44 |
| WORK1 r | .09 | .05 | -.06 | .27 | .10 | .05 |
| p | .68 | .82 | .78 | .21 | .64 | .81 |

Spearmans correlations.
Only patients with valid RG and LES data on all 4 occasions (n=24) were included in the analysis.

Appendix 27: Correlation of life events discrepancy score with change in profile RG measures (method 1) (N=24).

| | | Session Pairing | | | | | |
|---|---|---|---|---|---|---|---|
| Variable | | 1v2 | 2v3 | 3v4 | 1v4 | 2v4 | 1v3 |
| PHYS | r | .09 | .14 | -.31 | -.13 | -.15 | -.11 |
| | p | .68 | .53 | .14 | .53 | .49 | .61 |
| COG | r | -.23 | -.38 | -.12 | -.24 | -.41 | -.27 |
| | p | .28 | .07 | .58 | .26 | .04 | .21 |
| EMOT | r | -.11 | -.06 | -.22 | -.04 | .01 | .05 |
| | p | .61 | .77 | .31 | .86 | .96 | .82 |
| SOC | r | .11 | -.17 | -.25 | -.04 | -.15 | .14 |
| | p | .61 | .44 | .80 | .86 | .48 | .50 |
| WORK | r | .16 | .05 | -.01 | .05 | -.17 | .21 |
| | p | .46 | .80 | .97 | .80 | .43 | .32 |

Spearmans correlations.
Only patients with valid RG and LES data on all 4 occasions (n=24) were included in the analysis.

Appendix 28: Frequency measures (mean, SD, median, range) for Glboal Rating Scale (GRS)

| | | Session | | | |
|---|---|---|---|---|---|
| Variable | Statistic | 1 | 2 | 3 | 4 |
| GRS1 | Mean (SD) | 2.2 (0.9) | 2.3 (0.9) | 2.1 (0.9) | 2.2 (1.1) |
| | Med (Range) | 2 (1-4) | 2 (1-4) | 2 (1-4) | 2 (1-4) |
| GRS2 | Mean (SD) | 2.3 (1.2) | 2.2 (1.1) | 2 (1.1) | 1.8 (0.9) |
| | Med (Range) | 2 (1-5) | 2 (1-4 ) | 2 (1-4) | 2 (1-4) |
| GRS3 | Mean (SD) | 2.4 (1.4) | 2.1 (1.2) | 2 (1.1) | 2 (1.1) |
| | Med (Range) | 2 (1-5) | 2 (1-4) | 2 (1-4) | 2 (1-5) |
| GRS4 | Mean (SD) | 2 (1) | 2.2 (1.3) | 2 (1.1) | 2.3 (1.1) |
| | Med (Range) | 2 (1-5) | 2 (1-5) | 2 (1-5) | 2 (1-4) |
| GRS5 | Mean (SD) | 2.4 (1.2) | 2.3 (1.5) | 2 (1.1) | 1.8 (1) |
| | Med (Range) | 3 (1-5) | 2 (1-5) | 2 (1-5) | 2 (1-5) |
| GRS6 | Mean (SD) | 1.8 (0.9) | 1.9 (1.2) | 1.8 (1) | 1.8 (1) |
| | Med (Range) | 2 (1-4) | 2 (1-5) | 1.5 (1-4) | 1 (1-4) |
| GRS7 | Mean (SD) | 2.6 (1.4) | 2.8 (1.4) | 2.3 (1.2) | 2.3 (1.2) |
| | Med (Range) | 3 (1-5) | 3 (1-5) | 2.5 (1-5) | 2 (1-4) |

Group numbers: S1=25, S2=25, S3=24, S4=25

GRS1, general life satisfaction; GRS2, satisfaction with physical abilities; GRS3, satisfaction with cognitive abilities; GRS4, satisfaction with emotional status; GRS5, satisfaction with social life; GRS6, satisfaction with employment; GRS7, satisfaction with finances; Med, median; SD, standard deviation.

Note 1: 5 point rating scale used ranging from 1 (Very satisfied) to 5 (Very dissatisfied ie. higher score = greater dissatisfaction.

Appendix 29: Frequency measures (mean, SD, median, range) for Sickness Impact Profile (SIP)

| Variable | Statistic | Session 1 | 2 | 3 | 4 |
|---|---|---|---|---|---|
| Dimension Scores: | | | | | |
| AMB | Mean (SD) | 13.9 (16.3) | 13.3 (20.9) | 10.1 (10.9) | 12.1 (12.8) |
| | Med (Range) | 8 (0-63) | 5.4 (0-91) | 5.4 (0-31) | 9.3 (0-40) |
| MOB | Mean (SD) | 13 (12.8) | 10.9 (9.6) | 9.4 (13) | 6.9 (8.9) |
| | Med (Range) | 7.9 (0-45) | 10.5 (0-26) | 6.3 (0-51) | 6.3 (0-37) |
| BCM | Mean (SD) | 9.4 (10.9) | 8.6 (11.4) | 6.8 (12.7) | 7 (9.3) |
| | Med (Range) | 4.8 (0-35) | 4.1 (0-42) | 0 (0-50) | 3.5 (0-28) |
| SI | Mean (SD) | 14.7 (14.5) | 14.4 (16.6) | 14 (19.7) | 9.2 (11.1) |
| | Med (Range) | 10.7 (0-65) | 9.4 (0-73) | 7 (0-87) | 7 (0-55) |
| COM | Mean (SD) | 20 (18.1) | 18.9 (17.5) | 17.2 (17) | 11.4 (16.9) |
| | Med (Range) | 15.3 (0-74) | 13.9 (0-60) | 11.6 (0-46) | 7.4 (0-59) |
| AB | Mean (SD) | 19.7 (18.4) | 19.6 (21.2) | 13.2 (21.7) | 13.1 (17.2) |
| | Med (Range) | 16.7 (0-80) | 12.6 (0-79) | 6.8 (0-100) | 7 (0-69) |
| EM | Mean (SD) | 16 (19.6) | 15.3 (17.8) | 15.1 (14.3) | 12 (16) |
| | Med (Range) | 10.5 (0-87) | 8.5 (0-77) | 12.1 (0-47) | 8.4 (0-71) |
| SR | Mean (SD) | 16.9 (23.6) | 11.9 (15.8) | 18 (24.9) | 11.6 (11.8) |
| | Med (Range) | 10.4(0-100) | 10.4 (0-67) | 10.4(0-100) | 10.4 (0-39) |
| EAT | Mean (SD) | 1.9 (3.1) | 4.9 (5.5) | 3.3 (5.4) | 2.2 (3.9) |
| | Med (Range) | 0 (0-11) | 4.9 (0-20) | 0 (0-21) | 0 (0-12) |
| WORK | Mean (SD) | 22 (31.2) | 18.4 (28.7) | 18 (27.6) | 23.6 (33.1) |
| | Med (Range) | 11.2(0-100) | 11.1(0-100) | 11.1(0-100) | 13.6(0-100) |
| HM | Mean (SD) | 11.8 (17) | 6.3 (10.6) | 12.4 (20.2) | 5.1 (8.1) |
| | Med (Range) | 7.9 (0-78) | 0 (0-46) | 7.3 (0-91) | 0 (0-32) |
| REC | Mean (SD) | 14.5 (22.3) | 13.3 (14.9) | 9.2 (14.7) | 15 (18.1) |
| | Med (Range) | 8.2 (0-100) | 8.2 (0-66) | 7.1 (0-60) | 8.2 (0-68) |
| Category Scores: | | | | | |
| PHYS | Mean (SD) | 11.4 (10.2) | 10.4 (9.4) | 8.3 (10.1) | 8.3 (8.2) |
| | Med (Range) | 6.1 (0-34) | 5.7 (0-29) | 4.6 (0-37) | 6.4 (0-26) |
| SOC | Mean (SD) | 17 (11.8) | 16.7 (14.8) | 14.6 (15.4) | 10.9 (11.2) |
| | Med (Range) | 16.6 (2-49) | 14.6 (0-54) | 9.2 (1-71) | 6.9 (0-42) |
| SIP | Mean (SD) | 13.8 (10.7) | 12.4 (8.8) | 11.5 (11.9) | 9.5 (8.1) |
| | Med (Range) | 9.8 (2-41) | 12.5 (1-35) | 7.7 (1-53) | 7.4 (1-29) |

Group numbers: S1=26, S2=25, S3=24, S4=25

AMB, ambulation; MOB, mobility; BCM, bodycare and movement; SI, social interaction; COM, communication; AB, alertness behaviour; EM, emotions; SR, sleep and rest; EAT, eating; WORK, work; HM, household management; REC, recreation; PHYS, overall physical disability score; SOC, overall psychosocial disability score; SIP, total disability score.

Notes: scores calculated as percentage disability score with maximum dysfunction indicated by 100% disability score

Appendix 30: Frequency measures (mean, SD, median, range) for Mood Adjective Checklist (MACL)

| Variable | Statistic | Session 1 | 2 | 3 | 4 |
|---|---|---|---|---|---|
| Anxiety | Mean (SD) | 2.1 (2.1 ) | 1.9 (2.4) | 1.9 (2.6) | 1.4 (1.9) |
| | Med (Range) | 2 (0-9) | 1.5 (0-11) | 1 (0-12) | 1 (0-6) |
| Fatigue | Mean (SD) | 2.4 (2.1) | 2.7 (2.4) | 2.3 (2.8) | 2.4 (2.4) |
| | Med (Range) | 2 (0-8) | 2 (0-8) | 1.5 (0-11) | 2 (0-8) |
| Host. | Mean (SD) | 1.3 (2.7) | 1 (2) | 1.2 (2) | 0.7 (1.4) |
| | Med (Range) | 0 (0-11) | 0 (0-8) | 0 (0-6) | 0 (0-5) |
| Vigour | Mean (SD) | 4.2 (2.9) | 4.7 (2.8) | 4.5 (2.5) | 4.7 (2.9) |
| | Med (Range) | 4 (0-10) | 4 (0-9) | 4 (0-9) | 5 (0-10) |
| Dep. | Mean (SD) | 2.5 (3) | 3.5 (5.2) | 2.5 (3.1) | 2 (3) |
| | Med (Range) | 1 (0-10) | 1 (0-22) | 1 (0-13) | 0 (0-11) |

Group numbers: S1=26, S2=26, S3=24, S4=25

Med, median; SD, standard deviation; Host., hostility; Dep., depression.

Appendix 31: Frequency measures (mean, SD, median, range) for Life Events Schedule (LES)

| Variable | Statistic | Session 1 | 2 | 3 | 4 |
|---|---|---|---|---|---|
| POS | Mean (SD) | 1.9 (1.8) | 1.5 (1.5) | 1.3 (1.5) | 1 (1.2) |
| | Med (Range) | 0-6 | 0-4 | 0-5 | 0-5 |
| NEG | Mean (SD) | 1.3 (1.3) | 1 (1.7) | 0.7 (0.8) | 0.7 (1.2) |
| | Med (Range) | 0-5 | 0-7 | 0-3 | 0-4 |
| DISR | Mean (SD) | -0.6 (2) | -0.4 (2) | -0.6 (1.5) | -0.3 (1.9) |
| | Med (Range) | -5, 5 | -4, 3 | -5, 2 | -4, 4 |

Group numbers: S1=26, S2=26, S3=24, S4=23

Med, median; SD, standard deviation; POS, positive events score; NEG, negative events score; DISC, negative-positive discrepancy score

Appendix 32: Global rating scale: summary of 1-way anova by gender (session 4 data, epilepsy patients)

| Variable | ALL EPILEPSY PATIENTS (21 male:4 female) | | MATCHED GROUP (4 male: 5 female) | |
|---|---|---|---|---|
| | F | p | F | p |
| GRS1 | 0.0004 | 0.98 | 0.09 | 0.77 |
| GRS2 | 1.17 | 0.29 | 0.27 | 0.62 |
| GRS3 | 1.93 | 0.18 | 0.24 | 0.64 |
| GRS4 | 0.86 | 0.36 | 1.47 | 0.26 |
| GRS5 | 0.47 | 0.50 | 0.07 | 0.80 |
| GRS6 | 1.34 | 0.26 | 0.18 | 0.68 |
| GRS7 | 0.02 | 0.90 | 0.08 | 0.79 |

GRS1, general life satisfaction; GRS2, satisfaction with physical abilities; GRS3, satisfaction with cognitive abilities; GRS4, satisfaction with emotional status; GRS5, satisfaction with social life; GRS6, satisfaction with employment; GRS7, satisfaction with finances.

Appendix 33: Sickness Impact Profile scores: summary of Mann-Whitney analysis by gender (session 4 data, epilepsy patients).

| Measure | ALL EPILEPSY PATIENTS (33 male:6 female) | | MATCHED GROUP (6 male: 9 female) | |
|---|---|---|---|---|
| | Z | p | Z | p |
| AMB | -1.50 | 0.13 | -1.02 | 0.31 |
| MOB | -2.22 | 0.03 | -2.06 | 0.04 |
| BCM | -1.27 | 0.20 | -0.54 | 0.59 |
| SI | -0.04 | 0.97 | -0.59 | 0.55 |
| COM | -0.25 | 0.80 | -0.55 | 0.58 |
| AB | -0.08 | 0.93 | -0.42 | 0.67 |
| EM | -0.65 | 0.51 | -0.12 | 0.91 |
| SR | -0.20 | 0.84 | -0.44 | 0.66 |
| HM | -0.42 | 0.67 | -0.73 | 0.46 |
| EAT | -0.12 | 0.91 | -0.84 | 0.40 |
| REC | -0.40 | 0.69 | 0.00 | 1.00 |
| WORK | -1.48 | 0.14 | -0.60 | 0.55 |
| PHYS | -1.79 | 0.07 | -0.83 | 0.41 |
| SOC | 0.00 | 1.00 | -0.83 | 0.41 |
| SIP | -0.19 | 0.85 | -0.24 | 0.81 |

AMB, ambulation; MOB, mobility; BCM, bodycare and movement; SI, social interaction; COM, communication; AB, alertness behaviour; EM, emotional status; SR, sleep and rest; HM, household management; EAT, eating; REC, recreation; WORK, work; PHYS, composite physical disability score; SOC, composite psychosocial disability score; SIP, composite total disability score.

Appendix 34: MACL: summary of 1-way anova by gender (session 4 data, epilepsy patients).

| Measure | ALL EPILEPSY PATIENTS (35 male:8 female) | | MATCHED GROUP (4 male: 5 female) | |
|---|---|---|---|---|
| | F | p | F | p |
| Anxiety | 5.23 | 0.03 | 3.25 | 0.09 |
| Fatigue | 1.95 | 0.17 | 0.23 | 0.64 |
| Hostility | 1.33 | 0.25 a | 0.67 | 0.43 b |
| Vigour | 0.29 | 0.59 | 0.65 | 0.44 |
| Depression | 1.22 | 0.28 | 1.24 | 0.28 |

a Also ran Mann-Whitney statistic for this sub-scale due to non-normality of distribution of hostility scores. Non-significant effect of gender seen ($Z=-1.06$, $p<.29$).

b Mann-Whitney result: $Z=-0.21$, $p<.84$.

Appendix 35: Life Events Scale scores: summary of Mann-Whitney analysis by gender (session 4 data, epilepsy patients).

| Measure | ALL EPILEPSY PATIENTS (36 male:8 female) | | MATCHED GROUP (8 male: 9 female) | |
|---|---|---|---|---|
| | Z | p | Z | p |
| POSITIVE | -0.60 | 0.55 | -0.30 | 0.76 |
| NEGATIVE | -0.03 | 0.97 | -0.38 | 0.71 |
| TOTAL | -0.25 | 0.80 | -0.29 | 0.77 |
| DISCREPANCY | -0.09 | 0.93 | -0.45 | 0.66 |

POSITIVE, positive life event score; NEGATIVE, negative life event score; TOTAL, total life event score; DISCREPANCY, life event discrepancy score (positive events minus negative events).

Appendix 36: Correlation of negative life events with change in GRS ratings (epilepsy patients, N=22).

| | | Session Pairing | | | | | |
|---|---|---|---|---|---|---|---|
| Variable | | 1v2 | 2v3 | 3v4 | 1v4 | 2v4 | 1v3 |
| GRS1 | r | .45 | .14 | -.004 | .05 | .04 | -.02 |
| | p | .03 | .53 | .99 | .83 | .85 | .95 |
| GRS2 | r | .005 | .27 | .17 | -.33 | .06 | .07 |
| | p | .98 | .22 | .44 | .14 | .79 | .75 |
| GRS3 | r | -.44 | .002 | .38 | -.09 | .08 | -.30 |
| | p | .04 | .99 | .08 | .68 | .72 | .17 |
| GRS4 | r | -.20 | .23 | -.17 | -.07 | .23 | -.06 |
| | p | .38 | .30 | .46 | .75 | .31 | .78 |
| GRS5 | r | .006 | .28 | .01 | -.12 | .30 | -.16 |
| | p | .98 | .20 | .95 | .59 | .17 | .49 |
| GRS6 | r | -.10 | .01 | .11 | .30 | .05 | .16 |
| | p | .67 | .96 | .64 | .18 | .81 | .47 |
| GRS7 | r | .42 | -.14 | -.27 | -.11 | -.27 | .11 |
| | p | .05 | .54 | .23 | .63 | .22 | .62 |

Spearmans correlations.
Only patients with valid GRS and LES data on all 4 occasions (n=22) were included in the analysis.

Appendix 37: Correlation of positive life events with change in GRS ratings (epilepsy patients, N=22).

| | | Session Pairing | | | | | |
|---|---|---|---|---|---|---|---|
| Variable | | 1v2 | 2v3 | 3v4 | 1v4 | 2v4 | 1v3 |
| GRS1 | r | .08 | -.11 | .17 | .16 | .01 | .39 |
| | p | .71 | .63 | .45 | .49 | .96 | .08 |
| GRS2 | r | -.31 | .23 | .19 | -.16 | .19 | .18 |
| | p | .16 | .30 | .39 | .50 | .39 | .44 |
| GRS3 | r | -.01 | .20 | .08 | .06 | .25 | -.10 |
| | p | .95 | .37 | .71 | .80 | .27 | .65 |
| GRS4 | r | -.28 | -.04 | -.007 | -.33 | -.002 | -.46 |
| | p | .21 | .87 | .98 | .13 | .99 | .03 |
| GRS5 | r | -.39 | -.06 | -.05 | -.22 | -.26 | -.37 |
| | p | .07 | .78 | .82 | .33 | .25 | .10 |
| GRS6 | r | .34 | .53 | .18 | .25 | .42 | .09 |
| | p | .12 | .01 | .42 | .27 | .05 | .69 |
| GRS7 | r | .16 | .10 | .27 | -.11 | -.10 | .17 |
| | p | .48 | .66 | .23 | .63 | .66 | .45 |

Spearman correlations.
Only patients with valid GRS and LES data on all 4 occasions (n=22) were included in the analysis.

Appendix 38: Correlation of total life events with change in GRS ratings (epilepsy patients, N=22).

| Variable | | Session Pairing | | | | | |
|---|---|---|---|---|---|---|---|
| | | 1v2 | 2v3 | 3v4 | 1v4 | 2v4 | 1v3 |
| GRS1 | r | .26 | -.03 | .06 | .008 | .05 | .17 |
| | p | .24 | .90 | .78 | .97 | .82 | .46 |
| GRS2 | r | -.18 | .34 | .30 | -.23 | .24 | .13 |
| | p | .43 | .12 | .17 | .30 | .29 | .56 |
| GRS3 | r | -.21 | .19 | .34 | -.07 | .28 | -.25 |
| | p | .36 | .39 | .13 | .75 | .20 | .28 |
| GRS4 | r | -.38 | .04 | -.13 | -.26 | .03 | -.46 |
| | p | .08 | .86 | .57 | .24 | .90 | .03 |
| GRS5 | r | -.37 | .06 | -.08 | -.32 | .02 | -.41 |
| | p | .09 | .80 | .74 | .14 | .94 | .06 |
| GRS6 | r | .32 | .45 | .08 | .29 | .36 | .13 |
| | p | .15 | .03 | .73 | .20 | .10 | .57 |
| GRS7 | r | .32 | .08 | -.02 | -.07 | -.27 | .21 |
| | p | .14 | .74 | .91 | .77 | .23 | .34 |

Spearman correlations.

Only patients with valid GRS and LES data on all 4 occasions (n=22) were included in the analysis.

Appendix 39: Correlation of life event discrepancy score with change in GRS ratings (epilepsy patients, N=22).

| Variable | | Session Pairing | | | | | |
|---|---|---|---|---|---|---|---|
| | | 1v2 | 2v3 | 3v4 | 1v4 | 2v4 | 1v3 |
| GRS1 | r | -.19 | -.20 | .11 | .07 | -.03 | .34 |
| | p | .39 | .38 | .61 | .77 | .91 | .12 |
| GRS2 | r | -.32 | .02 | .01 | .10 | .09 | .10 |
| | p | .15 | .94 | .95 | .66 | .68 | .66 |
| GRS3 | r | .27 | .13 | -.21 | .05 | .13 | .16 |
| | p | .22 | .56 | .35 | .81 | .57 | .47 |
| GRS4 | r | -.02 | -.09 | .15 | -.27 | -.08 | -.35 |
| | p | .94 | .69 | .51 | .22 | .74 | .11 |
| GRS5 | r | -.27 | -.08 | .002 | -.20 | -.38 | -.10 |
| | p | .22 | .72 | .99 | .38 | .08 | .66 |
| GRS6 | r | .34 | .50 | .04 | .08 | .30 | -.03 |
| | p | .12 | .02 | .87 | .72 | .17 | .88 |
| GRS7 | r | -.15 | .12 | .37 | -.08 | .13 | -.20 |
| | p | .50 | .60 | .09 | .73 | .57 | .38 |

Spearman correlations.
Only patients with valid GRS and LES data on all 4 occasions (n=22) were included in the analysis.

Appendix 40: Correlation of negative life events with change in SIP scores (epilepsy patients, N=23).

| | | Session Pairing | | | | | |
|---|---|---|---|---|---|---|---|
| Variable | | 1v2 | 2v3 | 3v4 | 1v4 | 2v4 | 1v4 |
| Dimension scores: | | | | | | | |
| AMB | r | .34 | -.03 | .24 | .24 | .36 | .32 |
| | p | .11 | .88 | .26 | .27 | .09 | .14 |
| MOB | r | -.09 | -.27 | .42 | .04 | .39 | .12 |
| | p | .68 | .21 | .05 | .85 | .07 | .58 |
| BCM | r | -.13 | .43 | .42 | -.17 | .22 | -.09 |
| | p | .54 | .04 | .04 | .44 | .30 | .69 |
| SI | r | -.04 | -.25 | .51 | .07 | .43 | .01 |
| | p | .84 | .25 | .01 | .74 | .04 | .98 |
| COM | r | -.22 | -.13 | .35 | -.04 | -.02 | -.04 |
| | p | .30 | .56 | .11 | .86 | .93 | .86 |
| AB | r | -.01 | .10 | .50 | .23 | .30 | -.17 |
| | p | .98 | .65 | .02 | .28 | .16 | .45 |
| EM | r | -.09 | .04 | .41 | .06 | .29 | .26 |
| | p | .68 | .84 | .05 | .78 | .18 | .24 |
| SR | r | -.09 | .18 | .40 | .10 | .08 | -.19 |
| | p | .70 | .40 | .06 | .65 | .71 | .39 |
| EAT | r | .18 | .03 | .10 | .12 | .19 | -.20 |
| | p | .42 | .91 | .66 | .59 | .37 | .36 |
| REC | r | .32 | .12 | .21 | .14 | .48 | -.17 |
| | p | .13 | .60 | .34 | .53 | .02 | .43 |
| HM | r | .008 | -.02 | .26 | .06 | -.06 | -.28 |
| | p | .97 | .93 | .23 | .78 | .78 | .19 |
| WORK | r | -.23 | -.33 | .17 | .11 | .07 | .21 |
| | p | .28 | .13 | .44 | .61 | .74 | .34 |
| Category scores: | | | | | | | |
| PHYS | r | .18 | .25 | .48 | -.20 | .31 | .12 |
| | p | .42 | .25 | .02 | .36 | .14 | .58 |
| SOC | r | -.22 | -.10 | .48 | .21 | .05 | .08 |
| | p | .31 | .66 | .02 | .34 | .81 | .73 |
| SIP | r | .05 | .09 | .61 | .16 | .21 | .20 |
| | p | .81 | .68 | .002 | .47 | .33 | .37 |

Spearmans correlations.

Only patients with valid SIP and LES data on all 4 occasions (n=24) were included in the analysis.

Appendix 41: Correlation of positive life events with change in SIP scores (epilepsy patients, N=23).

| | | Session Pairing | | | | | |
|---|---|---|---|---|---|---|---|
| Variable | | 1v2 | 2v3 | 3v4 | 1v4 | 2v4 | 1v3 |
| Dimension scores: | | | | | | | |
| AMB | r | -.16 | -.15 | -.20 | -.16 | -.43 | .16 |
| | p | .47 | .49 | .35 | .47 | .04 | .46 |
| MOB | r | -.14 | -.29 | -.17 | .08 | -.27 | .29 |
| | p | .51 | .18 | .45 | .70 | .21 | .17 |
| BCM | r | -.01 | .24 | -.18 | .12 | -.07 | .26 |
| | p | .95 | .27 | .42 | .59 | .75 | .23 |
| SI | r | -.25 | -.002 | -.33 | -.09 | -.27 | -.17 |
| | p | .26 | .99 | .12 | .69 | .21 | .44 |
| COM | r | .09 | .41 | .07 | .14 | .11 | .52 |
| | p | .69 | .05 | .75 | .54 | .61 | .01 |
| AB | r | -.14 | -.04 | -.03 | -.21 | -.43 | .003 |
| | p | .51 | .85 | .91 | .33 | .04 | .99 |
| EM | r | .13 | -.30 | -.27 | .31 | .04 | .12 |
| | p | .55 | .17 | .22 | .15 | .86 | .58 |
| SR | r | -.17 | .23 | -.007 | .18 | .11 | -.29 |
| | p | .44 | .28 | .98 | .41 | .61 | .18 |
| EAT | r | -.21 | .11 | .04 | .09 | .36 | -.08 |
| | p | .35 | .63 | .85 | .67 | .09 | .73 |
| REC | r | -.13 | -.13 | -.46 | .02 | -.16 | -.04 |
| | p | .55 | .56 | .03 | .93 | .47 | .87 |
| HM | r | .14 | .04 | .06 | .35 | .25 | .24 |
| | p | .54 | .86 | .79 | .10 | .24 | .28 |
| WORK | r | -.11 | .14 | -.05 | .14 | .29 | .32 |
| | p | .63 | .51 | .81 | .53 | .19 | .14 |
| Category scores: | | | | | | | |
| PHYS | r | .04 | .03 | -.33 | .21 | -.19 | .36 |
| | p | .85 | .90 | .13 | .35 | .38 | .09 |
| SOC | r | -.13 | -.07 | -.26 | .09 | -.20 | -.14 |
| | p | .55 | .74 | .23 | .68 | .36 | .54 |
| SIP | r | -.42 | .04 | -.26 | .01 | -.18 | -.01 |
| | p | .05 | .84 | .23 | .95 | .41 | .98 |

Spearmans correlations.
Only patients with valid SIP and LES data on all 4 occasions (n=24) were included in the analysis.

Appendix 42: Correlation of total life events with change in SIP scores (epilepsy patients, N=23).

| Variable | | Session Pairing 1v2 | 2v3 | 3v4 | 1v4 | 2v4 | 1v3 |
|---|---|---|---|---|---|---|---|
| Dimension scores: | | | | | | | |
| AMB | r | .05 | -.12 | -.02 | .01 | -.24 | .27 |
| | p | .83 | .60 | .91 | .96 | .27 | .22 |
| MOB | r | -.11 | -.34 | .10 | .24 | -.004 | .40 |
| | p | .62 | .11 | .65 | .27 | .99 | .06 |
| BCM | r | -.02 | .40 | .15 | .07 | .12 | .25 |
| | p | .92 | .06 | .50 | .74 | .59 | .25 |
| SI | r | -.21 | -.08 | .10 | .04 | .05 | -.08 |
| | p | .34 | .73 | .64 | .87 | .84 | .70 |
| COM | r | -.03 | .30 | .36 | .24 | .15 | .45 |
| | p | .90 | .16 | .10 | .28 | .49 | .03 |
| AB | r | -.13 | .000 | .34 | .06 | -.18 | -.05 |
| | p | .56 | .99 | .12 | .80 | .42 | .84 |
| EM | r | .14 | -.22 | .08 | .34 | .17 | .26 |
| | p | .53 | .33 | .73 | .12 | .44 | .23 |
| SR | r | -.12 | .27 | .27 | .25 | .15 | -.38 |
| | p | .60 | .21 | .21 | .26 | .50 | .07 |
| EAT | r | -.09 | .09 | .01 | .21 | .47 | -.11 |
| | p | .68 | .67 | .95 | .35 | .02 | .61 |
| REC | r | .04 | -.02 | -.20 | .25 | .11 | -.02 |
| | p | .86 | .93 | .35 | .25 | .61 | .93 |
| HM | r | .23 | -.01 | .27 | .38 | .18 | .13 |
| | p | .30 | .98 | .22 | .08 | .41 | .56 |
| WORK | r | -.18 | .02 | -.07 | .10 | .29 | .36 |
| | p | .42 | .92 | .75 | .65 | .17 | .09 |
| Category scores: | | | | | | | |
| PHYS | r | .20 | .14 | .02 | .03 | -.02 | .40 |
| | p | .36 | .53 | .92 | .88 | .91 | .06 |
| SOC | r | -.25 | -.04 | .15 | .32 | -.08 | -.01 |
| | p | .25 | .85 | .48 | .13 | .70 | .95 |
| SIP | r | -.24 | .12 | .25 | .19 | -.02 | .13 |
| | p | .27 | .60 | .26 | .39 | .93 | .55 |

Spearmans correlations.
Only patients with valid SIP and LES data on all 4 occasions (n=24) were included in the analysis.

Appendix 43: Correlation of life event discrepancy score with change in SIP scores (epilepsy patients, N=23).

| | | Session Pairing | | | | | |
|---|---|---|---|---|---|---|---|
| Variable | | 1v2 | 2v3 | 3v4 | 1v4 | 2v4 | 1v3 |
| Dimension scores: | | | | | | | |
| AMB | r | -.40 | -.16 | -.30 | -.24 | -.52 | -.11 |
| | p | .06 | .46 | .16 | .28 | .01 | .62 |
| MOB | r | -.06 | -.15 | -.39 | .05 | -.46 | .17 |
| | p | .79 | .51 | .07 | .81 | .03 | .44 |
| BCM | r | .14 | -.05 | -.45 | .20 | -.28 | .33 |
| | p | .51 | .81 | .03 | .36 | .20 | .13 |
| SI | r | .003 | .04 | -.50 | -.14 | -.52 | -.07 |
| | p | .99 | .87 | .02 | .52 | .01 | .77 |
| COM | r | .27 | .39 | -.14 | .12 | .14 | .30 |
| | p | .21 | .06 | .51 | .56 | .53 | .16 |
| AB | r | .01 | -.09 | -.34 | -.38 | -.49 | .04 |
| | p | .96 | .67 | .11 | .07 | .02 | .86 |
| EM | r | .03 | -.32 | -.46 | .17 | -.24 | -.18 |
| | p | .89 | .14 | .03 | .45 | .28 | .40 |
| SR | r | -.11 | .13 | -.23 | .05 | .02 | -.12 |
| | p | .61 | .57 | .29 | .81 | .93 | .59 |
| EAT | r | -.19 | .002 | -.09 | -.12 | .04 | .008 |
| | p | .38 | .99 | .67 | .59 | .87 | .97 |
| REC | r | -.33 | -.26 | -.43 | -.13 | -.46 | .009 |
| | p | .13 | .24 | .04 | .57 | .03 | .97 |
| HM | r | .13 | -.004 | -.08 | .21 | .26 | .36 |
| | p | .57 | .99 | .73 | .34 | .24 | .09 |
| WORK | r | .06 | .30 | -.19 | .03 | .16 | .14 |
| | p | .80 | .17 | .39 | .90 | .47 | .53 |
| Category scores: | | | | | | | |
| PHYS | r | -.05 | -.13 | .58 | .29 | -.40 | .29 |
| | p | .81 | .57 | .004 | .19 | .06 | .19 |
| SOC | r | .13 | -.13 | -.46 | -.03 | -.19 | -.24 |
| | p | .55 | .54 | .03 | .90 | .39 | .26 |
| SIP | r | -.20 | -.05 | -.56 | -.08 | -.31 | -.11 |
| | p | .36 | .81 | .006 | .71 | .15 | .63 |

Spearmans correlations.
Only patients with valid SIP and LES data on all 4 occasions (n=24) were included in the analysis.

Discrepancy score calculated as: positive events - negative events.

Appendix 44: Sickness Impact Profile: summary of paired t-tests comparing pre- and post-operative SIP scores in patients with trigeminal neuralgia.

| | SUCCESS | | FAILURE | |
|---|---|---|---|---|
| | t | p | t | p |
| AMB | 1.22 | .260 | 1.62 | .247 |
| MOB | 1.79 | .117 | 4.39 | .048 |
| BCM | 0.28 | .790 | 1.99 | .184 |
| SI | 2.54 | .039 | -0.42 | .715 |
| COM | 2.85 | .025 | 1.83 | .209 |
| AB | 2.06 | .078 | -0.15 | .892 |
| EM | 2.27 | .058 | -0.14 | .905 |
| SR | 2.99 | .020 | 1.00 | .423 |
| EAT | 1.55 | .166 | 1.00 | .423 |
| WORK | 2.16 | .067 | 1.23 | .342 |
| HM | 0.61 | .562 | 1.41 | .295 |
| REC | 1.78 | .118 | -0.05 | .962 |
| PHYS | 1.15 | .288 | 4.05 | .056 |
| SOC | 2.55 | .038 | 5.30 | .034 |
| SIP | 1.89 | .100 | 7.24 | .019 |

Dimension scores: AMB, ambulation; MOB, mobility; BCM, bodycare and movement; SI, social interaction; COM, communication; AB, alertness behaviour; EM, emotions; SR, sleep and rest; EAT, eating; WORK, work; HM, household management; REC, recreation.
Category scores; PHYS, overall physical disability score; SOC, overall psychosocial disability score; SIP, total disability score.

Appendix 45: Correlation of negative life events with change in MACL scores (epilepsy patients, N=24).

| | | Session Pairing | | | | | |
|---|---|---|---|---|---|---|---|
| Variable | | 1v2 | 2v3 | 3v4 | 1v4 | 2v4 | 1v3 |
| Anx | r | .45 | -.21 | .26 | .14 | .12 | .32 |
| | p | .03 | .33 | .21 | .52 | .57 | .13 |
| Fat | r | .12 | -.13 | .07 | -.19 | -.29 | -.11 |
| | p | .56 | .54 | .74 | .37 | .17 | .62 |
| Host | r | .29 | .01 | .40 | .24 | .21 | .17 |
| | p | .17 | .95 | .05 | .25 | .34 | .42 |
| Vig | r | -.21 | -.29 | .40 | .06 | -.46 | .11 |
| | p | .32 | .18 | .05 | .78 | .02 | .60 |
| Dep | r | .09 | -.17 | .25 | -.03 | .06 | .03 |
| | p | .67 | .43 | .25 | .88 | .76 | .91 |

Spearmans correlations.
Only patients with valid MACL and LES data on all 4 occasions (n=24) were included in the analysis.

Appendix 46: Correlation of positive life events with change in MACL scores (epilepsy patietns, N=24).

| | | Session Pairing | | | | | |
|---|---|---|---|---|---|---|---|
| Variable | | 1v2 | 2v3 | 3v4 | 1v4 | 2v4 | 1v3 |
| Anx | r | -.007 | -.05 | .17 | .13 | -.02 | .44 |
| | p | .98 | .82 | .43 | .56 | .94 | .03 |
| Fat | r | -.37 | .11 | .12 | -.02 | .21 | .13 |
| | p | .08 | .63 | .56 | .93 | .33 | .56 |
| Host | r | -.14 | .04 | .12 | -.03 | .07 | .12 |
| | p | .52 | .84 | .57 | .88 | .76 | .56 |
| Vig | r | -.11 | .19 | .18 | .15 | .37 | .14 |
| | p | .62 | .37 | .41 | .49 | .08 | .52 |
| Dep | r | -.08 | .08 | -.35 | -.22 | .08 | -.11 |
| | p | .70 | .72 | .10 | .30 | .71 | .61 |

Spearmans correlations.
Only patients with valid MACL and LES data on all 4 occasions (n=24) were included in the analysis.

Appendix 47: Correlation of total life events with change in MACL scores (epilepsy patients, N=24).

| | | Session Pairing | | | | | |
|---|---|---|---|---|---|---|---|
| Variable | | 1v2 | 2v3 | 3v4 | 1v4 | 2v4 | 1v3 |
| Anx | r | .19 | -.08 | .39 | .32 | .08 | .51 |
| | p | .37 | .71 | .06 | .13 | .70 | .01 |
| Fat | r | -.29 | .06 | .17 | -.25 | .04 | .07 |
| | p | .17 | .78 | .42 | .23 | .85 | .76 |
| Host | r | .09 | -.01 | .34 | .30 | .21 | .18 |
| | p | .66 | .96 | .11 | .15 | .33 | .41 |
| Vig | r | -.28 | .06 | .41 | .19 | .19 | .05 |
| | p | .18 | .78 | .05 | .38 | .36 | .82 |
| Dep | r | -.02 | -.01 | -.03 | -.18 | .09 | -.07 |
| | p | .94 | .97 | .88 | .40 | .69 | .75 |

Spearmans correlations.
Only patients with valid MACL and LES data on all 4 occasions (n=24) were included in the analysis.

Appendix 48: Correlation of life event discrepancy score with change in MACL scores (epilepsy patients, N=24).

| | | Session Pairing | | | | | |
|---|---|---|---|---|---|---|---|
| Variable | | 1v2 | 2v3 | 3v4 | 1v4 | 2v4 | 1v3 |
| Anx | r | -.46 | .02 | -.02 | .01 | -.13 | .02 |
| | p | .03 | .94 | .93 | .96 | .55 | .94 |
| Fat | r | -.24 | .13 | .12 | .21 | .43 | -.001 |
| | p | .27 | .56 | .58 | .32 | .04 | .99 |
| Host | r | -.26 | .04 | -.15 | -.19 | -.04 | -.06 |
| | p | .22 | .86 | .48 | .37 | .87 | .79 |
| Vig | r | .12 | .35 | -.17 | .08 | .53 | .10 |
| | p | .57 | .09 | .42 | .72 | .007 | .63 |
| Dep | r | .006 | .20 | -.31 | -.20 | -.002 | -.24 |
| | p | .98 | .34 | .14 | .35 | .99 | .26 |

Spearmans correlations.

MACL, Mood Adjective Checklist; Anx, anxiety; Fat, fatigue; Host, hostility; Vig, vigour; Dep, depression; S1, baseline; S2, 1 month; S3, 3 months; S4, 6 months.

Note: Only patients with valid MACL and LES data on all 4 occasions (n=24) were included in the analysis.
Discrepancy score= LES positive events - LES negative events.

Appendix 49: Frequency measures (mean, SD, median, range) for Construct Importance Scale (CIS)

| Variable | Statistic | Session 1 | 2 | 3 | 4 |
|---|---|---|---|---|---|
| CIS1 | Mean (SD) | 3.9 (0.91) | 4.1 (0.95) | 3.88 (0.80) | 4.0 (0.96) |
| | Med (Range) | 4 (2-5) | 4 (2-5) | 4 (2-5) | 4 (2-5) |
| CIS2 | Mean (SD) | 4.2 (0.61) | 4.0 (0.83) | 3.8 (0.96) | 4 (0.94) |
| | Med (Range) | 4 (3-5) | 4 (2-5) | 4 (1-5) | 4 (2-5) |
| CIS3 | Mean (SD) | 3.7 (0.86) | 4.1 (0.82) | 4 (0.81) | 3.9 (0.70) |
| | Med (Range) | 4 (2-5) | 4 (2-5) | 4 (2-5) | 4 (2-5) |
| CIS4 | Mean (SD) | 3.5 (0.75) | 4.1 (0.79) | 4 (0.91) | 3.9 (0.97) |
| | Med (Range) | 4 (2-5) | 4 (2-5) | 4 (2-5) | 4 (2-5) |
| CIS5 | Mean (SD) | 3.3 (1.2) | 3.7 (1.2) | 4 (0.86) | 3.7 (1.2) |
| | Med (Range) | 4 (1-5) | 4 (1-5) | 4 (2-5) | 4 (1-5) |
| CIS6 | Mean (SD) | 3.7 (1.0) | 3.7 (1.2) | 3.8 (0.8) | 3.7 (1.0) |
| | Med (Range) | 4 (1-5) | 4 (1-5) | 4 (2-5) | 4 (2-5) |
| CIS7 | Mean (SD) | 3.5 (1.0) | 3.5 (1.0) | 3.5 (0.9) | 3.7 (0.7) |
| | Med (Range) | 4 (1-5) | 4 (2-5) | 3.5 (1-5) | 4 (3-5) |
| CIS8 | Mean (SD) | 3.9 (1.0) | 3.8 (1.3) | 3.8 (1.2) | 3.9 (0.7) |
| | Med (Range) | 4 (2-5) | 4 (1-5) | 4 (1-5) | 4 (3-5) |
| CIS9 | Mean (SD) | 3.9 (1.0) | 4.1 (0.9) | 4 (0.9) | 4 (0.9) |
| | Med (Range) | 4 (2-5) | 4 (2-5) | 4 (2-5) | 4 (2-5) |
| CIS10 | Mean (SD) | 3.8 (1.0) | 4 (0.8) | 4 (0.8) | 4.2 (1.0) |
| | Med (Range) | 4 (1-5) | 4 (2-5) | 4 (2-5) | 4 (2-5) |
| CIS11 | Mean (SD) | 4 (0.8) | 4.1 (0.8) | 4.1 (0.6) | 3.9 (0.8) |
| | Med (Range) | 4 (2-5) | 4 (3-5) | 4 (3-5) | 4 (2-5) |
| CIS12 | Mean (SD) | 3.6 (0.7) | 4.2 (0.7) | 4 (0.7) | 3.7 (0.7) |
| | Med (Range) | 4 (3-5) | 4 (3-5) | 4 (3-5) | 4 (2-5) |
| CIS13 | Mean (SD) | 4.1 (1.0) | 4.1 (1.0) | 3.8 (0.9) | 3.7 (1.2) |
| | Med (Range) | 4 (2-5) | 4 (2-5) | 4 (2-5) | 4 (1-5) |
| CIS14 | Mean (SD) | 3.6 (1.1) | 4.1 (0.9) | 3.7 (1.1) | 3.8 (0.9) |
| | Med (Range) | 4 (1-5) | 4 (2-5) | 4 (2-5) | 4 (2-5) |
| CIS15 | Mean (SD) | 3.9 (1.0) | 3.8 (1.1) | 3.5 (1.1) | 3.7 (1.2) |
| | Med (Range) | 4 (1-5) | 4 (2-5) | 4 (2-5) | 4 (1-5) |

Group numbers: S1=26, S2=25, S3=24, S4=25

Appendix 50: Construct Importance Scale scores: summary of Mann -Whitney analysis by gender (session 4 data, epilepsy patients).

| | ALL EPILEPSY PATIENTS (21 male:4 female) | | MATCHED GROUP (4 male: 5 female) | |
|---|---|---|---|---|
| Variable | Z | p | Z | p |
| CIS1 | -0.44 | 0.66 | -0.44 | 0.66 |
| CIS2 | -0.04 | 0.97 | 0.00 | 1.00 |
| CIS3 | -0.69 | 0.49 | -0.45 | 0.65 |
| CIS4 | -0.47 | 0.64 | -0.26 | 0.80 |
| CIS5 | -0.04 | 0.97 | -0.26 | 0.80 |
| CIS6 | -0.44 | 0.66 | -0.64 | 0.52 |
| CIS7 | -0.85 | 0.40 | -0.39 | 0.69 |
| CIS8 | -1.17 | 0.24 | -0.59 | 0.56 |
| CIS9 | -1.18 | 0.24 | -1.02 | 0.31 |
| CIS10 | -0.20 | 0.84 | -0.13 | 0.90 |
| CIS11 | -0.82 | 0.41 | -0.60 | 0.55 |
| CIS12 | -1.24 | 0.22 | -1.51 | 0.13 |
| CIS13 | -0.16 | 0.88 | -0.62 | 0.54 |
| CIS14 | -0.79 | 0.43 | -0.61 | 0.54 |
| CIS15 | -1.64 | 0.10 | -1.67 | 0.10 |